Exhibit 13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

Civil No. 19-2875 (RBK/JS)

THIS DOCUMENT APPLIES TO ALL CASES

HON ROBERT B. KUGLER

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Remote Videotaped via Zoom Deposition of MIN LI, Ph.D., commencing at 7:03 a.m. China Standard Time, on the 20th of April, 2021, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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Page 9

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz, I am a legal videographer for Golkow Litigation Services.

Today's date is April 20, 2021, and the time is 7:03 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL.

The deponent is Min Li, Ph.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Maureen Pollard, and will now swear in the witness.

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Page 10

MIN LI, Ph.D.,
having been duly remotely sworn, was examined and testified as follows:
EXAMINATION
BY MR. SLATER:
Q. Good evening.
A. Good evening. Yeah, I'm here. Actually, it's morning here.
Q. Okay. We're here to take your deposition. Do you understand that's the purpose of this proceeding?
A. Sure. Yes.
Q. Have you ever been deposed before?
A. No.
Q. This is a sworn proceeding in the United States District Court.
Do you understand that you're now under oath and must tell the truth?
A. Yes, I understand.
Q. If for any reason you are asked a question and don't feel like you either understand it or can answer it truthfully and accurately for any reason based on how the

Page 11

question was asked or what was asked, just tell me.
A. Sure.
Q. It may be that I mispronounce a word or use scientific jargon incorrectly. Whatever the case may be, you can just let me know what's unclear, and I can try to rephrase the question. Okay?
A. Okay. Great.
Q. During the course of the deposition, there will be objections and discussion between the attorneys. That's normal. That's people preserving the record for future use in the court.
It's not something that should throw you off; I just want you to know that might happen, okay?
A. Okay.
Q. And certainly there's no reason why any objection or statement by any attorney would be any sort of a prompt for you to say anything or not say anything. It's just the attorneys discussing their legal positions on different things.

Page 12

So certainly that's not something you would ever want to be doing, is taking a cue from an attorney's objection or anything they say.
Do you understand that?
A. Okay.
Q. What is your current title?
A. I'm the vice-president for analytical operation for Huahai Pharmaceutical Company, or also known as ZHP, particularly, you know, in this case.
MR. SLATER: Let's put up Exhibit 291, please, Cheryll.
(Whereupon, Exhibit Number ZHP-291 was marked for identification.)
MR. SLATER: Great. Thank you.
BY MR. SLATER:
Q. On the screen is the notice to take your deposition. Have you seen this document before?
A. Yes. Actually, I also have a copy, yes.
Q. Oh, you have a copy in front of

Page 13

you?
A. Yes.
Q. Okay. Did you familiarize yourself with the topics that you're going to be questioned about tonight --
A. Yes.
Q. -- and for the next several days?
A. Yes, I think so. You know, I try my best to be familiarize myself, yes.
Q. Did you prepare for this deposition?
A. Oh, yes.
Q. What did you do to prepare for the deposition?
A. Mostly receiving, you know, trainings from my, you know, lawyers.
And also I've talked to various peoples, you know, because a lot of details I need to, you know, find out from -- basically from my level, you know. Typically I have not been involved in too many details, particularly nontechnical issues.
Q. You said that you spoke with

Page 14

your attorneys; I think you called it training from your lawyers.
Who was it that you spoke with?
A. You know, here Patrick, and also Rick, Nason. Mostly, you know, those three. Sometimes, you know, there's other, like Seth.
Q. Did you speak to any attorneys in China in preparing for the deposition?
A. No. Because I'm a US citizen, I don't think it's legally obligated for me to talk to anybody, you know, or any lawyer, you know, in China.
Q. Did anybody tell you that?
A. Yeah. I mean, you know, the lady, you know, in the general -- you know, in the president office, you know, she's basically managing this. You know, that's what she told me, because she's being basically, you know, get in touch with, you know, the Chinese lawyer for my Chinese colleagues, because we want to make sure, you know, right, we have to be basically abide by, you know, you know, the Chinese law as

Page 15

well, because otherwise, you know, if you have any procedural violation, you know, you may get into big trouble.
Q. Who did you speak with in the president's office? You said you spoke with a woman about the deposition. Who was that?
A. Maggie, yeah. Maggie Kong. Yeah, yeah.
Q. Can you spell her name, please?
A. Last name is K-O-N-G. She usually goes by her English name, you know, Maggie, but also her Chinese name is Xiaofong, Xiaofong Kong.
Q. And when did you speak with her about the deposition?
A. That was long time. You know, I think in the very early phase. I don't remember exactly, you know, how long. Maybe, like, for several months.
Q. Was that the first time you spoke with anybody about this deposition?
A. I don't think so.
Q. Who was the first person you ever spoke to about the deposition?

Page 16

A. I really don't remember. Probably, I would assume most likely her, but I, you know, because it's such a long period, and I really cannot tell, like, who is exactly the first person, to be honest with you. I mean, I don't have photographic, you know, memory.
Q. When you say it's been "such a long period," can you estimate how long ago it was when you first spoke with someone about this deposition?
A. Maybe six months. I don't know. I mean, it's just a very rough estimate.
Q. Could it have been a year ago?
A. I mean, if you're talking about, you know, you know, starting collecting, you know, the document, yeah, I would say, yeah, that's about, you know, at least about a year ago, yes.
Q. When did you first find out your deposition was going to be taken?
A. I think sometime last year, because I -- you know, you know, she told me

Page 17

I will be one of the -- you know, the witness, you know, will be, you know, giving the testimony. Sometime last year.
Q. So you think it was maybe a year ago?
A. I wasn't sure. As I said, I wasn't sure exactly, you know, but sometime last year, okay?
Q. Well, right now it's April 19th here in the States, so are we talking last April? Are we talking last summer? Are we talking before April? Do you recall?
A. As I said, I don't have accurate recollection.
Q. Do you have a calendar that you keep that would show you when you were first notified that you were going to be deposed?
A. I don't keep that particular calendar, like particularly when was the first day that I received the notice. Because I -- you know, from my perspective, you know, you know, that's not important. I mean, the important thing is I know what's the date and I need to prepare.

Page 18

Q. I wasn't asking you what was important. I'm just asking you if you remember when it was.
A. I don't remember exactly date. I told you, you know, a few times already.
Q. Did you receive an e-mail about this deposition back in the beginning?
A. Yeah, I think so. Yeah, I received an e-mail. You know, if I go back to my, you know, you know, e-mail, I mean, I may be able to tell you tomorrow, you know. You know, after this session I can, you know, if you really wanted to have that.
Q. That would be great if we could have an understanding of when you first learned about --
A. Okay.
MR. GALLAGHER: Object to the extent that -- we'll take it under advisement. Object to the extent it calls for any privileged information.
BY MR. SLATER:
Q. You said the first person you ever spoke to about being deposed was Maggie

Page 19

Kong, is that correct?
A. I would say likely.
Q. Who else in your company have you spoken to about the deposition?
A. I mean, what do you mean by -- you know, speaking about what?
Q. Anything having to do with the deposition, either the fact of the deposition, what you were going to testify to, how to conduct yourself, obtaining information to testify. Anything connected to the deposition.
A. I talked to, you know, people, right? Particularly people who travel, you know, to, you know, you know, to Macao, right?
I talked to them about logistics, you know, about, you know, the procedural, you know, all the details, you know, the purposes just for me, you know, to be able to getting to Macao and to be participate in this, you know, testimony, you know. I just want to make sure, you know, things will be done as arranged, right?

Page 20

And also talk to, like, Peng Dong, you know, you know, Mr. Peng Dong, quite early on during, you know, you know, at the early phase of the preparation because I asked him something about, you know, the early -- you know, during the early stage, you know, you know, how that original, you know, you know, process, you know, was developed, you know, you know, the so-called zinc chloride, you know, process.
Q. Well, we'll go back through the names and what you spoke to them about, but let's try to get the list of names of people from your company you spoke to. So far we have Maggie Kong and we have Peng Dong.
Who else from your company did you speak to with regard to anything connected to the deposition?
A. I also talked to Qiangming Li, you know, as I said, mostly about logistics, getting into, you know, the hotel, you know, everything. Yeah.
Q. Who else?
A. Who else? And also talked to

Page 21

one of the staff under, you know, Qiangming Li and asking about some of the specifics.
Q. Who was that person?
A. His name is Jun Wang.
Q. Who else from your company have you spoken to with regard to the deposition?
A. I think that's about it.
Q. You said earlier you'd spoken to people in order to get some background information in order to testify.
Who were the people that you spoke to to get that background information to be able to testify on the topics you were designated on?
A. The background -- well, basically when I say "background" is, you know, actually I'm referring to, you know, to that particular topic regarding, you know, that process change, right?
So with that regard I was talking to, you know, Mr. Peng Dong during the early phase, you know, of the preparation.
Q. What else did you talk to Peng

Page 22

Dong about besides the process change? Anything?
A. No, that's it.
Q. What specifically did you discuss with Mr. Dong regarding --
A. I just -- I was asking him, you know, who basically was involved, you know, in that process change.
He said he was not clear because, you know, he probably was not involved, you know, during that process, I mean.
Q. So you spoke to Peng Dong about the process change, you asked him who was involved, and he said he didn't know because he wasn't involved, and that was the conversation?
A. Yeah, pretty much, yeah. Basically, you know, I was asking him, like, who basically was the original sort of, like, you can call, like, inventor or whatever, like who developed that process.
Q. And what did he tell you?
A. He said, you know, you know,

Page 23

you know, he didn't know.
Q. Can you tell me who was the inventor of the process change, the zinc chloride process change?
A. Well, the -- you know, from the document, right, from the document, you know, at least some of the document, I know the technology was originated from SynCore, okay, which is a subsidiary of Huahai Pharmaceutical.
But I was just asking him who, you know, that individual, like specifically who that individual was.
Q. And he didn't know?
A. He didn't -- yeah, he didn't know.
Q. Did you ask anybody else?
A. No.
Q. Did you speak to anybody from SynCores?
A. No.
Q. Why not?
A. I mean, for me, you know, I mean, there's no need for me to go more

Page 24

deeper, you know, because I'm not a, you know, a process chemist.
MR. GALLAGHER: I'm going to object to the line as outside the scope of the 30(b)(6) topics, but certainly --
MR. SLATER: Patrick, you're saying that my questioning about how he prepared himself to testify for the 30(b)(6) topics is outside the scope of the 30(b)(6) topics?
MR. GALLAGHER: No, no.
MR. SLATER: Because that's what I'm doing.
MR. GALLAGHER: Proceed.
BY MR. SLATER:
Q. How long did this discussion with Peng Dong take?
A. Just very briefly over the phone, yeah.
Q. Okay. How long did it take?
A. Maybe five, ten minutes.
Q. So let me -- rephrase.
Did you say you also spoke to

Page 25

Mr. Qiangming Li?
A. Yes. About the logistics, traveling into Macao.
Q. Did you talk to Qiangming Li about anything substantive about your testimony?
A. No.
Q. Did you ask him any questions about something you might testify about?
A. No.
Q. The staff member Jun Wang, when did you speak to that person?
A. Not Jun Wang. It's Jun, yeah. J -- Jun Wang or Jun Wang.
Q. I'll ask it again.
When did you speak to Jun Wang?
A. Just a few days, like, let me see, just two, three days before I came over to Macao, yeah, because I just wanted to try to clarify some of the, you know, you know, chronology of the events, you know, for some of the customers, you know, you know, or their discussion.
Because, you know, he was the

Page 26

main person doing the analytical investigation from the QC side, so I just, you know, tried to ask him some of those, you know, you know, you know, details like, you know, how many customers, you know, you know, like been having this.

You know, some of those, you know, early on we characterized them as like technical exchange, right, and then later on, you know, it's being formally characterized as a customer complaint.

Well, basically, you know, talking about, you know, these unknown peaks, you know. Yeah. So I was just trying to, you know, you know, find out who -- like when, you know, like the -- you know, what the, you know, their question, you know, was.

Q. When you say "the unknown peaks," do you mean the unknown peaks that later were identified as nitrosamine peaks?

A. No. Actually all of the peaks, all of the peaks, right, after I review, you know, those documents, right, all of the peaks people talking about between Huahai's

Page 27

customer and, yeah, all of those peaks, you know, that discuss that specifically they're not nitrosamine.

I mean, obviously, I mean, you know, you know, retrospectively maybe one of the tiny -- you know, now we know, right, nitrosamine, you know, you know, it could co-elute with one of the backgrounds. But that's only, you know, you know, after, you know, the facts, you know, after.

And then when you spike, you know, the standard sample or reference sample of the NDMA, you know, with a very high, like, concentration, then you -- you know, retrospectively you can say, hey, you know, the NDMA could co-elute, you know, after, you know -- actually on the shoulder of the one background peaks.

But all of the -- you know, all of the peaks, you know, people were talking about, you know, retrospectively we know, you know, they are not NDMA or anything, you know -- you know, any other, you know, nitrosamines.

Page 28

Q. When you say that it can co-elute with a background peak, are you talking about the toluene peak?

A. No. Actually, there was one little peak after the toluene peak.

Q. And the little peak after the toluene peak turned out to be the nitrosamine peak, correct?

A. Oh, no, no. Actually, that peak -- well, that peak in the background, okay -- it's a little bit complicated. Okay. In the background -- so that peak is also eluted in the blank injection, okay?

And then in the sample injection, this peak turns out -- if I remember correctly, this peak turns out to be n-butyl acetate, okay?

So that's the peak -- that's the peak, you know, eluting after the toluene peak. Okay. So NDMA would elute on the shoulder, or sometimes may even completely co-elute with this peak.

Q. When did you speak to Jun Wang? You said two to three days before you came to

Page 29

Macao. When was that?

A. I came here on the 18th. Yeah. So it would be like, you know, around the 16th, yeah.

Q. The 16th would have been Friday?

A. Yes, is 16 Friday? Let's see. Yeah, it's Friday, yes.

Q. How long did you talk to Jun Wang about this deposition?

A. It's probably 15, 20 minutes.

Q. Did you review any documents to prepare for the deposition?

A. Did I review any documents? Yes.

Q. What did you review to prepare for the deposition?

MR. GALLAGHER: Let me just -- give me a minute, Min.

To counsel not to disclose the substance of conversations that you had with attorneys.

MR. SLATER: I didn't ask anything about attorneys.

Page 30

THE WITNESS: Okay.
MR. GALLAGHER: You asked about documents he reviewed, which he may have done with attorneys, so I'm just -- he can answer the question. I'm just going to caution him not to disclose the substance of conversations he had with attorneys.
Please answer the question.
A. I mean, there are quite a few documents here. Yeah, for example, some of the --
BY MR. SLATER:
Q. Let me ask it very clearly.
A. You know, regarding, you know, unknown peak investigations. And also like ICH documents, you know, and also some of our -- like SOPs, and also the deviation investigation reports. You know, I mean, there's a lot of stuff.
Q. Were you reading these documents for the first time?
A. No. Many of -- I mean, some of those, you know, obviously I read before, you

Page 31

know, like SOPs, ICH documents, you know. But some obviously, you know, that I read, you know, the very first time.
Q. You met with counsel how many times to prepare for deposition?
A. Oh, I think like five, six times.
Q. When is the first time you spoke to counsel about the deposition?
A. I don't recall.
Q. Give me your best estimate.
A. Let's say -- I have to think about it. It's -- you know, in the beginning it was like a weekly training, and then we -- you know, you know, before I came we skipped one, so I don't know how many.
Let's say -- hypothetically let's say six times, right? So the fifth time will be like a half-month ago, right?
So then I have another -- yeah, so roughly like one and a half months ago starting. But don't hold me accountable, you know, if it's a little bit off, you know. But as I said, it's in the ball park.

Page 32

Q. You said "before I came." What were you referring to?
A. Well, the 18th of April, I mean this last Sunday, came to Macao.
Q. So before you came to Macao, I wasn't clear, how many times did you say you spoke to counsel?
A. Totally, as I said, like five or six times.
Q. When was the first time you spoke to counsel in connection?
A. As I told you, by rough estimation, it probably was like maybe a month and a half ago. But as I said, it could be two months, you know. But it just seemed like a ball park.
Q. How much time did you spend in those meetings with counsel?
A. Usually I would say like about two hours roughly, average.
Q. Okay. Looking at the deposition right now, the deposition notice -- rephrase.
Looking at the deposition

Page 33

notice, let's go to the -- actually, you have it in front of you, right?
A. Yeah.
Q. On the second-to-last page of the deposition notice, there was a request for your most recent resume/curriculum vitae and your LinkedIn profile.
A. Uh-huh. I already provided it.
Q. And those are the most recent versions of both?
A. Yes.
Q. This also asked for the complete production of any relevant custodial documents for you, "including those maintained on personal computers or electronic devices, to the extent not produced prior."
Are you producing any documents in connection with the deposition at this time?
A. No.
Q. You started working with ZHP in 2014, right?
A. Yes. September of 2014, yes.

Page 34

Q. Were you given any sort of a computer at that time to do your work for ZHP?
A. Yes.
Q. What type of computer were you given when you started?
A. Originally it's a ThinkPad, Lenovo ThinkPad, but that computer broke down. Now I have a Microsoft, like what, ProBook.
Q. You said you were given a Lenovo ThinkPad when you started, and then it broke. When did it break?
A. When did it break. That's a very good question. It broke during -- actually during a trip. I don't remember exactly.
When did it break. Probably somewhere between 2017 to 2018, but, you know, I don't have an accurate, you know, recollection exactly, like, which year.
Q. When your computer broke, did you notify your company that you needed a new computer?

Page 35

A. Oh, yeah, mm-hmm.
Q. Who did you notify?
A. IT.
Q. And they got you a new computer?
A. Yes.
Q. There would be a record within the company of you asking for a new computer and getting that computer. I assume something like that gets documented, right?
A. Oh, sure, sure, uh-uh.
Q. So if we need to know when your computer broke and when you got your new computer, the company should be able to provide that information, right?
A. Yeah. If I ask, they should be able to provide, yes.
MR. SLATER: Counsel is going to ask me to send an e-mail or something after the deposition to confirm the request, but that's going to be another one of the things we're going to request.
MR. GALLAGHER: Please put it in writing, and we'll take it under advisement.

Page 36

BY MR. SLATER:
Q. When you said the computer broke on a trip, what happened to the computer?
A. It just could not start, so I think eventually it turns out to be, you know, a hard drive failure.
Q. What happened to the data that was on the computer?
A. I would say, according to the IT guys -- well, quite a few documents actually became permanently damaged, but the majority of them was able to be restored, yeah.
Q. You said documents were permanently damaged?
A. Some of the documents, yeah, because of the hardware, you know, failure.
Q. What types of documents were permanently damaged?
A. Well, it's -- you know, there's different kinds.

Page 37

Q. Well, tell me, please, which ones?
A. Like some of those, like, research papers, you know, some of those research, you know, you know, investigation report. And even, you know, some personal, you know, like pictures.
Q. Was your computer backed up periodically?
A. What do you mean, "backed up"? Like backed up to, like, an external drive?
Q. I mean backed up so that the data was held in a separate location so that if your computer stopped working, the data wouldn't be lost.
A. I -- you know, I didn't do that.
Q. Is there any protocol in your company to back up computers periodically?
A. Well, for important documents, you know, you know, the company have archive, so I don't need to, you know, you know, to archive like, you know, by myself.
Q. How about your e-mails? Were

Page 38

any of your e-mails lost when your computer broke?
A. No. E-mail, you know, it's always there, e-mail, you know, because it's always in the server.
That's, you know, that's what the IT -- you know, at least, you know, it will be preserved according to the company policy, you know, for as long as the company policy, you know, you know, would allow.
Q. What does the company policy require?
A. I don't have the specifics.
Q. You've been there since 2014. Is it your understanding that all the e-mails you've sent or received have been backed up or held on a server?
A. As I said, yeah, I mean, as long as, you know, you know, the company, you know, policy says, you know, how long it will keep, you know, in company server, it will be there. You know, so that regardless, you know, my personal computer's failure, it will be there.

Page 39

Q. Has there ever been a time since your computer broke where you realized that a document or any data was lost and you couldn't retrieve it, couldn't find it?
A. No. I always be able to retrieve, you know, from either my e-mail or from, you know, you know, company's archive, or from my colleagues, you know.
Q. The ThinkPad, is that a desktop or is that a laptop or something else?
A. Laptop. Nobody use desktop anymore, as far as I know, I mean, you know, for personal use.
Q. Well, in your work at ZHP, have you had a desktop computer in addition to the laptop?
A. No.
Q. Never had a desktop computer?
A. I think it's totally obsolete for the purpose, you know, you know, people doing office work. I mean, at least for me, I mean.
Q. I'd like to be a little more precise on the timing of when your computer

Page 40

broke, if you can recall. Otherwise we're obviously going to make our request, but it might help.
Did it occur in -- you said -- well, rephrase.
With regard to when your computer broke, was that in 2017, or was that in 2018?
A. As I said, just around that period. I need to -- I need to -- you know, as I said, I'll talk to my IT guys, you know, you know. They will have the record, right, when the replacement happened.
Q. When you -- rephrase.
When your Lenovo ThinkPad broke, did you say that you got a Microsoft ProBook --
A. Yes.
Q. -- as your new computer?
A. Yes.
Q. And that's another laptop?
A. Yes.
Q. Is that the same computer, the one you use today?

Page 41

A. Yes.
Q. So --
A. Well, no. I'm sorry, no. Hold on, hold on. This is -- no. This is the company's -- you know, you know, the solely dedicated computer, you know, right? What we're talking about right now, okay?
What I'm saying is, you know, you know, the PC or the laptop I'm using for my business, right, or company business, yeah, is a Microsoft, you know, ProBook, okay?
Q. During the time you've worked at ZHP, have you also owned other computers for personal use, other than the Lenovo ThinkPad and the Microsoft ProBook?
A. No.
Q. Did you use the ThinkPad and the ProBook -- rephrase.
Did you use the Lenovo ThinkPad not only for company business, but also for personal e-mail?
A. No, I don't think so. I mean, only maybe for -- let me see. Did I -- for

Page 42

personal -- I cannot guarantee, like, I haven't, like, receive a single, like, a personal e-mail. But I can say usually I don't use that for, you know, you know, for personal e-mails, okay.

Q. What computer -- during the time -- rephrase.

During the time you had the Lenovo ThinkPad, what computer did you use for your personal e-mails?

A. Well, the personal e-mail -- let's see. The personal e-mail -- well, I used the personal e-mail, you know, through the web, right, to access my personal e-mail.

I mean is that, is -- to me, you know, you know, I wasn't sure that constitutes as the personal use of the Microsoft, you know, you know, you know, like the ProBook.

Q. Let's try to take this one step at a time.

When you had the Lenovo ThinkPad, you had a ZHP e-mail address, right?

Page 43

A. Yes, uh-huh.

Q. Did you also have a personal e-mail address not related to your work?

A. Yes, I have a personal e-mail address.

Q. Did you use that personal e-mail through the Lenovo ThinkPad?

A. Yes. Sometimes, yes.

Q. Did you ever use the personal e-mail for business?

A. I don't think so. There may be very -- maybe, you know, very few occasions, right, one or twice, somehow, you know, some of the e-mail, you know, may just get crossed over.

You know, because sometimes when you type, you know, you know, the e-mail address, you know, you know, some of these will automatically show up, because my personal e-mail address has some parts of the e-mail address similar to my company e-mail address; for example, like the words "Min Li."

Q. You're saying somebody could

Page 44

try to send an e-mail to you to your work e-mail, and because "Min Li" is in your e-mail address, it would come to your personal e-mail?

A. No, no, no, no. What I'm just trying to say is sometimes if I, you know, you know, try to, like -- you know, sometimes when I send an e-mail I, you know, also maybe want to cc myself.

And so when I type, you know, my company's, you know, you know, e-mail address, you know, my personal e-mail address, you know, sometimes may accidentally be typed in, you know.

Q. On the Microsoft ProBook, have you used your personal e-mail?

A. I also, as I said, access my personal e-mail accounts from time to time. You know, that's pretty much, you know, you can say that I use, you know, that computer for personal use.

Q. Did you use your personal e-mail on the Microsoft ProBook for business e-mails?

Page 45

A. No.

Q. Do you know if either of your computers was taken into the control of either IT or your lawyers to be searched in order to pull off documents in connection with this litigation?

A. My Microsoft ProBook, yes, was taken into, yeah, that purpose, yes.

Q. When?

A. They have gone through, yeah, my personal ProBook, yes.

Q. When?

A. I think sometime last year. Again, you know, I have so many things ongoing, you know, I don't remember exactly. Yeah. It should be sometime last year.

Q. Sometime in 2020?

A. It looks like. But again, you know, like I said, I need to, you know, find out. If you really wanted that exactly date, I think -- you know, or exactly period, I can find out for you.

Q. Well, I want your best recollection right now. We may request that

Page 46

also. But what's your best recollection, that your computer was taken in order to take documents off it for this litigation in 2020?
A. Yeah, I think it should be sometime last year.
Q. Who was it that did that? Who approached you?
A. Who approached me.
Again, this whole activity from Huahai or ZHP's perspective, it was coordinated, again, by Maggie Kong.
Q. So if Maggie Kong keeps good records, she probably knows when everybody was first told about their depositions and when people were told to bring their computers in to be swept?
MR. GALLAGHER: Sorry. I'm going to object to the extent you're asking for information that would constitute attorney/client privileged information.
MR. SLATER: How would that be privileged? I'm asking this witness about another person he works with,

Page 47

who is not a lawyer.
MR. GALLAGHER: To the extent there was attorney/client privileged information in those discussions, I caution him not to disclose that.
BY MR. SLATER:
Q. Did you ever use your personal e-mail to talk to anybody -- well, rephrase.
Do you know if your personal e-mail was collected -- well, rephrase.
Do you know if your personal e-mail was reviewed to see if work e-mails were on your personal e-mail?
A. I'm sorry, it's -- could you rephrase?
Q. Sure.
Do you know whether any e-mails on your personal e-mail that related to your work at ZHP were pulled off the computer and provided to us?
A. I don't know, because I don't -- I don't know what being pulled off. I have no idea.
Q. And just so I understand, in

Page 48

terms of your personal e-mail, what do you have, a Yahoo and a Hotmail address? You use both of those?
A. I just have a Yahoo as my, you know, active, you know, you know, e-mail.
I mean, you know, you know, from years ago may have some other, you know, but those, you know, essentially they are that e-mail, I mean, right? Like many years ago I may have like an AT&T, you know, e-mail, but only -- I would say only, you know, live personal e-mail is my Yahoo e-mail.
Q. And that would be minli88@yahoo.com?
A. Yes.
Q. From 2014 to now, is that the only e-mail address that you've used for your personal e-mail?
A. Yes.
Q. Do you also have a smartphone of some type that you use for work?
A. I have my personal phone.
Q. What type of phone is that?

Page 49

A. It's a Huawei smartphone.
Q. Can you spell that for me, please?
A. Huawei, H-U-A-W-E-I. Huawei is the leading smartphone company in China.
Q. How long have you had the Huawei phone?
A. I have my current phone since last year.
Q. What did you have before last year?
A. What I had before last year, I had another Huawei, but that one had some issue, so I switched to the current one.
Q. What was the issue with that phone?
A. The -- it's quite a funny -- the -- you know, you know, the screen pops off. It's not completely pops off, but it just -- you know, I never see something like this before. You know, you know, the screen, the center of the screen, it just swells. And it's still usable, you know, but it's just -- it feels like it can broke down any

Page 50

time, so, yeah, so I just switched to another one. Yeah.
Q. How long did you have that phone for, the swelling phone?
A. The swelling phone, maybe two, three years.
Q. What did you have before that?
A. Before that I had a Samsung smartphone.
Q. Was the Samsung phone the one you were using as of 2014 when you joined ZHP?
A. That was, yes.
Q. What happened to the Samsung phone?
A. That phone was -- initially it had some battery problem, you know, essentially it was very difficult or even sometimes even impossible to charge.
Sometimes, you know, when the battery completely dead and you may be able to recharge a little bit, but then eventually to the point it become completely, you know, you know, you cannot charge, so it's just

Page 51

dead.
Q. Did you ever have a different phone that you used in the United States versus the phone you used in China?
A. I have a phone that I use, yeah, in the US.
Q. Which phone is that?
A. It's another Samsung.
Q. That's the phone you have currently?
A. Currently I have two phones. One, you know, you know, I mostly for, you know, for the phone calls, you know, or sometimes for the phone messages, you know, receiving from the United States.
And, you know, you know, for everything else, you know, that I use my China-based phone, because that's the best -- that's the best way, you know, you have to deal with.
Q. So the Samsung phone you currently have that you use for phone calls and phone messages, how long have you had that phone?

Page 52

A. How long I get that phone. That's a good question.
That should be -- let's see. I would say probably end of 2013, something like that.
Q. So the Samsung phone that you have for your phone calls and phone messages you had when you joined ZHP?
A. But at the same time I, you know, I bought, you know, the other -- well, actually, let's see.
I used another Samsung phone, you know, you know, turned that into, you know, you know -- yeah, I don't remember, you know, the other Samsung phone that I either -- that I bought in China or that I bought in the US.
But anyhow, you know, I was having two Samsung phones, okay. One is, as I said, that I still use today, but mostly for phone calls or messages to/from United States, okay.
The other phone, as I said, I don't remember either that I bought it in the

Page 53

US or bought it in China. But I used the other one -- you know, during, you know, the period that I joined ZHP, I used the other one as my personal phone in China.
Q. The Samsung phone that you currently have, am I correct that that was the phone that you were using back when you joined ZHP in 2014, the Samsung phone?
A. That phone was also -- yeah, that phone was also there, yeah. I mean, that phone, fortunately, is still working. Maybe -- you know, maybe I -- you know, you know, maybe the reason it's still working is that I didn't use that much, you know what I'm saying? It's only for, you know, you know, for checking, you know, sometimes for checking the phone messages, you know, sending, you know, you know, phone messages.
Q. How about sending text messages and receiving text messages?
A. Oh, yeah, yeah. When I say in sending phone messages, what I mean is actually mostly for sending text messages.
Q. And those text messages would

Page 54

relate to work and for personal?
A. No, no. Mostly personally.
Q. Did you ever send text messages on your Samsung phone that you still have related to work?
A. No.
Q. Not once?
A. No.
Q. Did you ever send text messages on any other phone related to work?
A. No. I don't like, you know, text messages.
Q. Well, you had three different phones for work purposes. Did you ever send text messages related to work on any of those three phones?
A. No.
Q. Do you know if those phones, if any of your -- rephrase.
Do you know if any of your phones were taken by your company so that the information on the phones could be downloaded and then reviewed for production to us as part of the litigation? Did they take your

Page 55

phone or phones?
A. Did they take my phones. I don't think so. I don't remember. I don't remember if they did that.
Q. Did anybody ever tell you at any point that you needed to save your documents and information and not delete anything because of this litigation?
A. Oh, yes, mm-hmm.
Q. When was that?
A. The very first time, it must be two, three years ago, I think.
Q. How did you --
A. But again --
Q. Was it someone who spoke to you, or did you get something in writing?
A. Somebody sending through the e-mail. Yeah, I think it should be someone, you know, of, you know, Maggie Kong's staff, you know, one of her staff.
Q. Do you ever use WeChat?
A. Yes.
Q. How long have you been using WeChat?

Page 56

A. How long. For quite long.
Q. Do you use WeChat for work purposes?
A. No.
Q. Never?
A. Never. I mean, if you -- sometimes, you know, we use WeChat to do the -- sort of like, you know, like phone conversations. I don't know if you consider that's, you know, you know, for work purposes. You know, that will be, you know, the only, you know, only way.
MR. SLATER: Cheryll, you can take down the dep notice. That's fine.
Q. I don't understand, respectfully, what you just said, so I'll ask it again.
Have you ever used WeChat for purposes of your work for ZHP?
A. As I said, you know, sometimes we use WeChat sort of like as a -- you know, use that as a phone function.
Q. Okay.

Page 57

A. So if you consider that that's, you know, you know, as work related, that would be the only -- you know, only occasion.
Q. How often does that happen? Do you do that all the time or --
A. It happens -- I wouldn't say all the times, but it happens from time to time, yeah. Because, you know, you know, sometimes, you know, you know, the other, you know, colleague, maybe they're not accessible, only through the WIFI, you know. So during that circumstances, you know, WeChat, you know, may be, you know, the most effective way, you know, just to talk to them.
Q. Do you ever use the videoconferencing WeChat as part of your work?
A. No.
Q. You never have?
A. Never. I don't like the video function.
Q. Do you use videoconferencing in any other mode or from any other application

Page 58

for your work?
A. For other. I don't -- usually we just have teleconference, yeah, because, you know, using video function, it takes a lot of memory, you know, slow down the effectiveness of the communications.
Q. My question is this. Have you used videoconferencing as part of your work?
A. As I said, I don't recall it. You know, we -- as I said, we usually just, you know, do the audio conference.
Q. You said usually you do. Does that mean sometimes you do videoconference?
A. Well, because I don't remember, you know what I'm saying? There may be some -- maybe there's one time, you know, someone insisted for whatever the reason. But I just don't recall, okay?
Q. Do you share documents over WeChat?
A. No.
Q. Have you ever for work?
A. No, not for work. At least for me.

Page 59

Q. Do you know if your conversations on WeChat have been recorded?
A. I don't know. I mean, like, I don't notice there's any recording function imbedded, like, in WeChat.
As far as I know, you know, I never recorded any conversations, you know, but from the other side, whether they record or not, I have no idea.
Q. So you wouldn't, for example, be posting documents on WeChat? Coming back to that again. I just want to be clear.
Let me ask it more clearly. Have you ever posted documents or shared documents on WeChat?
A. No.
MR. SLATER: Let's go to the Exhibit 292, I guess it will be, the resume, please.
(Whereupon, Exhibit Number ZHP-292 was marked for identification.)
BY MR. SLATER:
Q. So on the screen is

Page 60

Exhibit 292. Is that your current resume, CV?
A. Yeah, mm-hmm.
Q. Is it accurate?
A. Yeah, it is accurate.
Q. I want to ask you a little bit about your work before you joined ZHP.
According to the document, you were employed by Merck & Company before you joined ZHP, is that correct?
A. Mm-hmm, yes.
Q. What was the work did you at Merck?
A. As I described, you know, I think, quite clearly in my summary -- yeah, can you go down a little bit? -- everything basically is pretty much in there.
MR. SLATER: Go all the way down, please.
A. I actually worked, you know, you know, for Merck twice, right, first starting from 1998 through 2005, and then 2005 to -- you know, I switched to Schering-Plough. And by the end of 2009,

Page 61

Schering-Plough was acquired by Merck, so essentially, or effectively, I went back to Merck.
Could you enlarge, you know, the text a little bit? Yeah.
Yeah, basically, you know, you know, I -- when I was at Merck or Schering-Plough or after, you know, after the merger, I have a group of scientists that, you know -- you know, working in my teams.
We, you know, pretty much as I said, you know, do the atypical -- manufacturing atypical and all of the scientific investigations, analytical method development, validation, manufacturing process, you know, improvement.
And, you know, the main focus was to do the drug degradation mechanism studies and also elucidation of the structures of drug degradation products, utilizing various LC-MS.
As I listed here Thermo LTQ/Orbitrap, you know, Waters MALDI-TOF, and Waters Q-Tof, you know, these are all the

Page 62

different, you know, types of, you know, LC, you know, liquid chromatography, mass spectrometry instrument utilized for, you know, impurity, structure elucidation purposes.

Q. Did you ever --

A. I -- I'm sorry, go ahead.

Q. Did you ever -- rephrase.

Did you ever have any involvement with Merck's losartan formulations?

A. No.

Q. You mentioned -- well, rephrase. I want to ask you about a few things in your resume, some of the terminology.

One of things you say about your time at Merck is that your laboratory was "very well equipped with state-of-the-art analytical instruments including 9 mass spectrometers of different capabilities."

A. Right.

Q. During what time period did you have that state-of-the-art --

Page 63

A. That was mostly study from 2005, and that was the time that I joined Schering-Plough.

So since my joining, I start to, you know, establish and also was expanding my, you know, my team.

So eventually, I think two to three years into that time, like I would say around, you know, maybe 2008, I have these full set of, you know, equipments.

Yeah, I would say, yeah, because 2009 we already -- end of 2009 we already acquired by Merck. Yeah, so it's somewhere around 2008, the instrument capability of my team reached to -- you know, essentially to, you know, to a peak.

Q. You mentioned drug degradation studies. What is a drug degradation study?

A. Well, anything well decomposed over time, you know, it's -- the difference is just, you know, to the extent. Some are very stable, but still they may decompose, you know, a little bit. Some will decompose more obviously than the others, right?

Page 64

So essentially, you know, a drug molecule at the time, it will, you know, disintegrate, you know, become somebody else. So we need to identify, you know, those unknown impurities and, you know, to know, you know, what they are, and in order to better control them or to understand how they would form, why, you know, they would form.

Q. Would these studies be performed as part of a risk assessment before the manufacturing process or during the manufacturing process?

A. No, no. Actually, when I was at the Merck, also at Schering-Plough, my team was supporting commercialized products, okay?

So all of the events, they happened many years after these products were launched. Even for the commercial product they were on the market for 30, 40 years.

Over time was the improvement of analytical methods and also the improvement of the -- you know, the sensitivity of the methods, new impurity, you

Page 65

know, will emerge or will -- you know, they actually sometimes, in some, you know, cases, you know, those impurities, they've always been there; it's just because, you know, the old methodology was not sensitive or specific enough. You know, they were just there, you know, undetected.

But then one day, you know, sometimes by a rather, you know, coincidental, you know, you know, factors, you know, they become known. So, yeah, so then my team quite often will be called in to do the investigation.

Q. Do you recall any specific examples of those decomposing chemicals that Merck had found, where it had been happening for a long time and your company didn't know it?

A. Oh, yeah. Oh, yeah. I can give you one example. For that example we also published a paper, actually. Yeah.

So there was one product, it containing a, you know, drug substance, or also we can call it active pharmaceutical

Page 66

ingredients.
You know, that API was betamethasone dipropionate, okay, which is a steroids, you know, anti-inflammatory, you know, you know, steroids. It's a lotion product, okay, as far as I can remember.
And the reason that I can remember is because that was the -- that was the first, you know, significant investigation my team was working on, right?
So there was, you know, a known degradation product, okay? So that degradation product was a hydrolytic, you know, degradation product. It's called 21-monopropionate of betamethasone.
And at this degradation product -- I'm sorry.
This degradation product has always been known. You know, they eluted at one particular place, right? And then all of a sudden there was one day in the QC lab, it just happened to be maybe that one particular column has slightly better resolution than the others, right, and that peak is splitted

Page 67

into two peaks, okay? It just barely, you know, you know, split it, right?
And according to the SOP of the QC lab, once you have the splitting on a -- you know, you know, on a particular peak, right, you have to do investigation, right? Because according to the SOP, you have to do what we call a drop line integration, right?
So basically, then, the major one is still this monoester, which is a known degradant, but the other one become an unknown peak, right?
So then my, you know, my group did a comprehensive, you know, investigation using LC-MS and also utilizing NMR, and so finally we were able to find, you know, another degradant that has been unknown for this particular, you know, you know, drug substances.
And betamethasone dipropionate at the time, I think around maybe 2007 we did the investigation at, you know, Schering-Plough at the time, that product was already, I was told, on the market for like

Page 68

20, 30 years already.
So based upon the structure that we determined, then we start to search the literature, right? And then based upon the literature, you know, you know, this particular degradant, you know -- basically historical, you know, literature provided some clue as to how, you know, this degradation could come, right, or, you know, could happen.
But based upon, you know, you know, larger reasoning, we figured that this -- you know, the literature results cannot completely explain, you know, you know, the phenomenon that we see.
So based upon that and also, you know, and also based upon the stability results, we finally able to -- you know, to find out a new or a novel degradation mechanism from betamethasone dipropionate.
So we also, you know, provide -- actually published another paper specifically describing the -- you know, you know, this newly formed, you know,

Page 69

degradation mechanism, you know, even for a product that has been on the market for nearly 30 years.
There will still be, as I said, even with the progress, you know, of the technology, you know, better, you know, sensitivity, better, you know, specificity. You know, we're able to, you know, to find out, and also we're able to resolve those issues.
So after that --
Q. I'm sorry to interrupt. All I asked is if you recall any instances. I didn't ask you for the full story.
A. Okay. All right. Okay, sorry. Yeah, I thought you...
MR. GALLAGHER: Adam, we've been going about an hour and ten minutes. You can ask a few more questions, but maybe at some point we can take a break.
MR. SLATER: Whatever you want to do.
///

Page 70

BY MR. SLATER:
Q. I'm looking at your -- let's go to the first page, now, of the resume.
A. Sure.
So maybe after the resume question, we can take a break?
MR. SLATER: Why don't you go take the break now.
THE WITNESS: Okay. So we have what, 10, 15 minutes or what?
MR. SLATER: Let's go off the record, please.
THE VIDEOGRAPHER: The time right now is 8:12 a.m. We're now off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time right now is 8:27 a.m. We're back on the record.
(Whereupon, Exhibit Number ZHP-293 was marked for identification.)
BY MR. SLATER:

Page 71

Q. On the screen is Exhibit 293. Do you recognize that document?
A. Oh, yeah.
Q. What is it?
A. Right now it's just, you know, the starting of the summary of my LinkedIn page.
MR. SLATER: All right. Cheryll, can you scroll down to where it talks about -- right there. Perfect. No. A little more up. Yes, perfect.
Q. Your LinkedIn page says that you established something called CEMAT, C-E-M-A-T.
A. Yes, CEMAT.
Q. What is that?
A. Basically, it's just like -- you know, in the sense that I rebuilt my, you know, research team at Huahai.
You know, the mission is pretty much the same, you know, you know, in terms of, you know, supporting those issues related to pharmaceutical impurities, and those are

Page 72

the most challenging, you know, issues, as I put there, yeah, the most challenging technical issues.
Q. When I ask what CEMAT is, is it a laboratory or a separate office, or is it -- let me ask this question.
In terms of what CEMAT is, is it part of ZHP?
A. Yes.
Q. Where is it located?
A. It's located in headquarter of ZHP, E Linghai, Zhejiang Province, China.
Q. Which facility?
A. Which facility. It's in Xunqiao facility, yeah, Xunqiao site.
Q. Why was it necessary for you to establish CEMAT?
A. Why it's necessary?
Q. Let me ask the question very specifically.
What was the specific need -- well, rephrase.
What was the specific reason why CEMAT was established?

Page 73

A. Well, basically to improve, you know, the company's, you know, capability, you know, in this particular field.
Q. And that field would include the identification of impurities in drug products?
MR. GALLAGHER: Objection. Vague.
THE WITNESS: I'm sorry.
MR. GALLAGHER: You can answer.
THE WITNESS: Okay.
Yes, drug products as well as new drug substances.
BY MR. SLATER:
Q. Is API a drug substance?
A. Yeah. API, yeah, is another name usually for drug substance, yes.
Q. When I said "drug products," you were thinking finished dose?
A. Yes. That's usually people, you know, call it, yes.
Q. The identification of impurities in drug substances is an important part of cGMP, correct?

Page 74

MR. GALLAGHER: Objection. Vague.
You can answer.
THE WITNESS: Okay.
A. Identification is -- yes, it's part of the cGMP requirements, yes.
MR. SLATER: Cheryll, let's put up the next exhibit, this PowerPoint that we have regarding CEMAT, just to identify it for a moment. I believe it's ZHP00404315 to 327.
(Whereupon, Exhibit Number ZHP-294 was marked for identification.)
A. The exhibit is gone? Okay.
BY MR. SLATER:
Q. Do you see the PowerPoint we've put on the screen?
A. Yeah, sure.
Q. Did you create that PowerPoint?
A. My associates probably prepared a draft and then I finalized it, yes.
Q. What was the purpose of creating this PowerPoint?

Page 75

A. Well, there's multiple purposes. You know, one, just to present to, you know, our colleagues, you know, and sometimes, you know, present to, you know, to my boss, you know, during the, like, quarterly meetings, you know, particularly in the early days.
You know, you need to, you know, you need to show, you know, right, what you can achieve.
MR. SLATER: I'm sorry. Let's go to the page after the cover page, please? Perfect.
Q. Looking at the Mission of CEMAT, it says, "To solve the most challenging technical problems encountered from research and development to scale up and manufacture of drug substances and finished products, particularly those related to process impurities, degradation products, and solid state and polymorphism."
Do you see that?
A. Mm-hmm, sure.
Q. When this -- rephrase.

Page 76

Process impurities would include, for example, the NDMA created by the zinc chloride process; that's a process impurity, correct?
A. Retrospectively, yes.
Q. And the creation of NDMA and NDEA in the TEA process with sodium nitrite quenching, those would be process impurities, correct?
A. Right.
Q. And in both those -- rephrase.
After both those manufacturing processes -- well, rephrase.
For the zinc chloride process, the root cause of the creation of NDMA was that the dimethylformamide was decomposing to create dimethylamine, which then reacted during the process with nitrous acid to create NDMA, correct?
MR. GALLAGHER: Objection. Vague, and foundation.
BY MR. SLATER:
Q. That's the root cause, correct?
A. Yeah, that's the root cause

Page 77

retrospectively after, you know, the events occurred and we did quite a, you know, retrospective analysis, yes.
Q. And that retrospective analysis occurred when?
A. After the June 6th -- you know, when the events was first came out.
Q. Going to the TEA process with sodium nitrite quenching, the root cause for the NDMA and NDEA was that triethylamine hydrochlorothiazide was used as a catalyst. That substance then would give off or produce diethylamine or dimethylamine, and one or the other or both would then react with nitrous acid to create NDEA and NDMA.
That's the root cause in that manufacturing process, correct?
MR. GALLAGHER: Objection. Vague, foundation, and compound.
You can answer.
A. Okay. The root cause, I think actually, based upon my understanding, they are slightly different.
The -- you know, the reason

Page 78

that I'm saying that is, you know, based upon all of the new knowledge, right, that accumulated by the industry, as well as, you know, from the regulators, okay?

For the formation for the TEA process, for the formation of the TEA, basically you have two mechanisms. One is the DEA is a typical process impurity of TEA, so DEA would also, yeah, would react with the nitrous acid to perform NDEA.

But also, according to, as I said, again, updated, you know, you know, information, the triethylamine could also react with nitrous acid, but the efficiency is not as high as the reaction with the TEA, right?

So -- yeah, so basically, you know, that's the mechanism for that process, okay, or the root cause.

And for NDMA, for its presence in the TEA process, and I think the root cause is the -- in some of the TEA raw material it may contain a trace amount of, you know, of dimethylamine, okay, so that's

Page 79

one root cause.

I think that there's another root cause for the presence of NDMA in the TEA process, which is from, you know, for -- as far as I remember, for very limited, you know, batch numbers. Because for some of the, you know, product, they were manufactured, you know, using the share line, you know, with the zinc chloride valsartan. And I think, you know, so for those limited number of batches, that's another root cause.

So I think that's pretty much, you know, yeah, the root cause, you know, you know, for the TEA process for NDMA and NDEA.

Q. When you refer to the shared production line, are you talking about cross-contamination?

A. Well, that's one way, you know, from some of the inspections, you know, you know, people use that phrase, but I would say, rather, it's carryover, you know, of some of the residual impurities.

Q. And when was that learned? When was that root cause figured out?

Page 80

A. It was during, you know, again, part of the retrospective, you know, investigations.

And also those knowledge, you know, was not gained instantaneously. And obviously, you know -- I mean, it's like if you look at some of the FDA's -- their training material, FDA's announcement, you know, you know, this whole thing is very complicated, you know, so it takes time and great efforts, right?

So you will first, you know, reveal the most obvious, and then eventually, you know, when time goes by, you know. And so some of the other minor contributing factors was also being, you know, discovered.

Q. Before June of 2018, did ZHP ever have any information indicating that any of the valsartan manufacturing processes could cause any nitrosamine to be created?

A. No. The whole industry, as well as the regulator, did not have that knowledge, including ZHP.

Q. And I've seen some vocabulary

Page 81

in some things that I've read, so I just want to make sure we're on the same page as to what certain things mean as we go forward if we could, please.

A. No problem.

Q. So I've seen the term "nitrosamine" and I've seen the term "nitroso compound" or "N-nitroso compound."

Does that all basically mean the same thing?

A. No. To be scientifically precise, they are not the same.

Nitroso compound is a very -- you know, I'm a scientist, okay, right? If somebody just tell me nitroso compound, you know, you know, any compound have a nitroso group, they're called a nitroso compound. So nitrosamine is just a subtype of the nitroso compound, all right?

And the same thing, you know, N-nitroso compound is also a subtype of nitroso compound, but N-nitroso compound including the nitrosamine.

MR. SLATER: Cheryll, let's

Page 82

take this document down, and go to document -- now what are we up to, 294? Is the next document 294?
Is the next exhibit 294?
THE STENOGRAPHER: 295.
MR. SLATER: 295. I'm always off by one, Maureen.
(Whereupon, Exhibit Number ZHP-295 was marked for identification.)
MR. SLATER: Looking at Exhibit 295, let's put up ZHP00190573.
BY MR. SLATER:
Q. This is an e-mail dated July 27, 2017.
Do you see that?
A. Okay.
Q. Do you see the date in the top right?
A. Let's see. Yeah, uh-huh.
Q. And you can see the person who wrote it up in the top left. You can see Jinsheng Lin.
Do you see that?

Page 83

A. Yes. He was, yeah, one of my staff, yes.
Q. What was his role? What was his title?
A. His title right now is technical associate director, I think. Something like that, yeah.
Q. Would it have been the same title back in July of 2017?
A. No. He had one -- at least one promotion. He maybe at the time was like assistant, you know, like technical director, you know, but I don't, you know, keep those things, you know, you know, you know, up and running all the time in my mind. Yeah. But he -- yeah, he is one of the key technical person in my team.
MR. GALLAGHER: Adam, do you have an English language version of this document?
MR. SLATER: We do. I think Cheryll can put it into that.
MR. GALLAGHER: Into the link? Great.

Page 84

MR. SLATER: The link, the hopper.
(Whereupon, Exhibit Number ZHP-296 was marked for identification.)
A. That will be better for most of you guys. Yeah, for me that's fine, but...
MR. SLATER: Okay if I proceed?
MR. GALLAGHER: Yes, please. I see it. It's up.
BY MR. SLATER:
Q. So it says -- rephrase.
This e-mail dated by one of your key technical people, Jinsheng Lin, it says it's to multiple people. And I just -- tell me if I get these names right. Jucai Ge, Tianpei Huang, Wangwei Chen, Wenquan Zhu.
A. Okay.
Q. Wenbin Chen.
A. Uh-huh.
Q. Mr. Li.
A. That's me. Yeah, that's me.
Q. Peng Dong?
A. Wait a second. Oh, wait. I'm

Page 85

still seeing the Chinese version. Are you reading the English version?
Q. I'm certainly not reading the Chinese; I'm reading the English. But I'm just going through the names right now.
A. Yeah, sure. Yeah, go ahead.
Q. So we just -- we established you're one of the people who received this e-mail, correct?
A. Oh, yes.
Q. Also Peng Dong?
A. Mm-hmm.
Q. Lihong Lin?
A. Mm-hmm.
Q. Yanfeng Liu?
A. Yes, that's pretty close.
Q. Peng Wang?
A. Penh Wang, yes.
Q. And Wenling Zhang.
A. Yes.
Q. Okay. And it looks like the subject is "Valsartan Impurity K."
Does it say that, or is that an attachment?

Page 86

A. Yeah, "Valsartan Impurity K," yes.
Q. Okay. So the subject is "Valsartan Impurity K," correct?
A. Yes, looks like, yes.
Q. And this is to -- it's addressed to Ms. Ge. Is that pronounced right, G-E, Ge?
A. Yeah, yeah. Yes. That's perfect almost, yes.
Q. And they're talking about impurity they see in one of the production processes, correct?
A. Yeah, mm-hmm.
MR. SLATER: And let's turn to the second page now of the document, please, at the top.
Q. Tell me if I have this pretty much correct. At the top it says, "Through the secondary mass spectrometry analysis" -- and I want to stop there.
What is secondary mass spectrometry analysis?
A. It's basically you have --

Page 87

well, actually, you know, you have three stages. You're going to the -- first the mass detector, right? It's looking for the parent molecule away, or the parent most usually like protonated molecular eye.
And then you're going to a collision cell, you know, you know, you know, usually with gas, either nitrogen, helium, or, you know, some other gas, and to break them apart.
And then you have, you know, a number of, you know, you know, what do we call it, fragments, right? And then you go to another, you know, mass detector. Yeah. So sometimes it's also called a triple quad mass spectrometry, but sometimes just called MS2 or /MS.
Q. Again starting -- rephrase.
Starting at the top, it says, "Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO compound; it is similar to the

Page 88

N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic. Its possible formation route is shown as follows," and then we have the diagrams.
Did I get that right?
A. Yeah, yeah, it looks like.
Q. And if we go further down below the pictures, there is the second paragraph after the pictures.
MR. SLATER: You can keep scrolling down, please, Cheryll.
Q. Looking now at the second paragraph under the diagrams, the e-mail says, "If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk. This is a common problem in the production and synthesis of sartan APIs. It is recommended to improve other quenching processes (such as NaClO) along with the optimization of the valsartan sodium azide quenching process."
Did I get that pretty much

Page 89

right?
A. Yeah, it sounds like. Yeah.
Q. And then going to the last paragraph of this e-mail you received July 27, 2017, it says, "I've also attached a patent of a 2013 sodium azide NaClO quenching method by Zhejiang Second Pharma Co., Limited. They proposed that the use of NaNO2 quenching will result in the formation of N-NO impurities. At the same time, they used ZHP's crude Valsartan in their LC-MS test and detected this impurity. This indicates that other companies have paid attention to the quality problem very early on. So leaders please pay attention to this issue."
And then it's signed Jinsheng Lin, CEMAT, July 27, 2017, correct?
A. Yeah, looks like, uh-huh.
Q. And if we go back up to the top now, just to reiterate a couple things, it said in part that what was being seen here was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite, correct? You saw that language up at the

Page 90

top?
A. Yes.
MR. GALLAGHER: Objection. Vague, and mischaracterizes the document.
BY MR. SLATER:
Q. And, therefore, as of July 27, 2017, you and others in your company knew that when valsartan was quenched with sodium nitrite, it was forming in NDMA, correct?
MR. GALLAGHER: Objection. Again, vague and mischaracterizes the document.
A. You know, you know, I have received a lot of e-mails, and it looks like my name was there. But somehow I don't know, you know -- you know, he didn't specifically follow up with me or brought that, you know, specifically to my attention.
BY MR. SLATER:
Q. Well, that's what the e-mail says, right?
A. Right, right, I know. Yeah, I know that my name was there, but I, you know,

Page 91

receive huge amount of e-mail.
Usually, you know, for something -- I told them if something, you know, you know, they feel important, they should remind me or, you know, you know, brought up, you know, to my attention.
Q. And going down further to that second-to-last paragraph we read, just to reiterate and walk through, Jinsheng Lin had written, "If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk."
That's what he wrote, correct?
A. That's what he wrote, but, you know, he's not a toxicologist, so I think that's his speculation.
Q. Well, certainly with regard to NDMA in valsartan, that would be, and turned out to be, a significant GMP problem when it was discovered outside of ZHP, correct?
A. Let me see. Which --
MR. GALLAGHER: Objection. Calls for speculation.

Page 92

You can answer, Dr. Li.
A. I'm sorry, what is the question again? Sorry.
BY MR. SLATER:
Q. Sure.
When people outside ZHP learned that the valsartan manufacturing process was creating NDMA, that was a significant GMP problem, correct?
A. Well, that's what he said, yes.
Q. And he also said this is a common problem in the production and synthesis of sartan APIs. So at that point people within ZHP knew that with the manufacture of their sartan APIs, nitrosamines were being created.
That's what he's referring to in this e-mail, correct?
A. That, it looks like, is the case.
Q. And then he says, "It is recommended to improve other quenching processes (such as NaClO)."
And if you could translate that

Page 93

for me, please.
A. I'm sorry, which one here?
Q. The NaClO. Is that sodium nitrite?
A. No. That's the -- no, that's another quenching reagent. No, it's not sodium nitrite.
Q. What is it?
A. It's one of the chloro-containing, you know, acid. This one is actually the main ingredient in bleach.
Q. Hypochlorite.
A. Yeah.
Q. Is that hypochlorite?
A. Yeah, I think it should be that one, yes.
Q. Let me ask it again then, now that I just figured it out with you.
With my -- all right. Let me rephrase.
He wrote, "It is recommended to improve other quenching processes, such as hypochlorite" -- that's actually bleach, right?

Page 94

A. Yes.
Q. -- "along with the optimization of the valsartan sodium azide quenching process."
So he's recommending that the sodium azide quenching process that you had been using be optimized, be improved, correct?
A. Looks like, yes.
Q. And going back to the next paragraph, he actually points out that he is attaching a patent, which we'll pull out in just a moment, from a 2013 sodium azide hypochlorite quenching method by a different company, Zhejiang Second Pharma Co., Limited.
That's another company in China, correct?
A. Yes.
Q. And, again, the NaClO, that's hypochlorite, which is bleach, correct?
A. Yes.
Q. And he says that that company "proposed that the use of NaNO2 quenching will result in the formation of N-NO

Page 95

impurities."
NaNO2 is sodium nitrite, correct?
A. NaNO2, yes.
Q. And N-NO impurities would be nitrosamine impurities, correct?
A. I'm sorry, which one?
Q. Where it says "N-NO," those would be nitrosamine impurities, correct?
A. I'm sorry. I don't know which you're referring to.
MR. SLATER: Scroll down a little, Cheryll. I think it's cut off.
Q. In the last paragraph?
A. Oh, yeah. Yeah, it's N-NO, yeah, impurity, yes. It's N-nitro impurity, yes.
Q. And he then says, "At the same time, they used ZHP's crude Valsartan in their LC-MS test and detected this impurity."
And "LC-MS," that would be liquid chromatography-mass spectrometry? Do I have that right?

Page 96

A. Yeah, mm-hmm.
Q. And again, as I'm going to show you in a moment, he's talking about what he read in this patent by this other company in China.
And he then says, "This indicates that other companies have paid attention to the quality problem very early on."
Do you see that?
A. Mm-hmm.
Q. And this quality problem he's talking about is the sodium nitrite quenching leading to the creation of nitrosamines, correct?
A. Looks like.
Q. And he then says, "So leaders please pay attention to this issue."
And when he's referring to "leaders," would that be the people on this e-mail, including yourself and Peng Dong and Lihong Lin, and the others on that e-mail?
MR. GALLAGHER: Objection. Vague, and calls for speculation.

Page 97

You can answer, Dr. Li.
A. Yeah, it looks like at least the two, yes.
BY MR. SLATER:
Q. Now let's go, if we could -- well, actually, let me ask you this question.
This e-mail -- we have something called metadata, and metadata is information we get when we get produced documents; where they came from, who authored them, etcetera. That's something we exchange as part of this litigation.
A. Okay.
Q. The metadata on this said that this came from a folder titled "Documents" from your old computer, which apparently, according to the metadata, was copied from your old desktop into your new computer in or about June 2018.
Do you remember doing that?
A. I'm sorry?
MR. GALLAGHER: Objection. Objection. Vague and foundation.
///

Page 98

BY MR. SLATER:
Q. Do you remember doing that, copying this document from one computer into another computer in or about June of 2018?
A. I didn't do that.
Q. So if that happened, somebody else would have done it, and that would have been stored in --
A. Probably IT, yeah. As I said -- yeah.
Q. So this e-mail clearly is -- rephrase.
So based on this e-mail, your company was -- well, let me rephrase this.
Did your company ever tell the FDA or any other regulators about its knowledge about the creation of nitrosamines including NDMA from the quenching with sodium nitrite?
Do you recall your company telling the FDA or any regulatory authorities about that?
A. Well --
MR. GALLAGHER: Objection.

Page 99

Vague.
A. In this particular case, you know, he's talking -- well, that particular case with, you know, irbesartan, right? And so he's, you know, you know, you know, making a kind of a, you know, you know, guess.
You know, I mean, all of the language that you can see, you know, you know, yeah, because the reaction, you know, that he showed is irbesartans, yeah.
BY MR. SLATER:
Q. Well, if we go to the top of this page --
MR. SLATER: Could you scroll up, please, Cheryll, the top of the second page? Thanks.
Q. -- just to be clear, he specifically said that "It is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite," and it's very toxic.
A. That's -- he's, you know, you know -- yeah, he's making a guess. Yeah, because -- because, you know, what he found is, you know, is this N-, you know, nitroso

Page 100

compound with irbesartan, yeah. It's not valsartan. But based upon that, yeah, it looks like he's making -- you know, making his guess.
Q. Well, he's comparing it and calling it similar to the NDMA that forms in valsartan when quenched with sodium nitrite.
That's what he said, right?
A. Yeah, that's -- again, you know, you know, that's his, you know, his guess or his speculation.
Q. Well, he doesn't say he's guessing or speculating, does he?
A. He didn't say, but basically from the context, you know, yeah. I mean, it's obvious.
Q. Well, it's also obvious he said in the second-to-last paragraph, if we scroll down to it, that "If it is confirmed as the above speculated structure in this irbesartan, then its toxicity will be very strong, and there will be an extremely high GMP risk."
Meaning if it's a nitrosamine,

Page 101

it's going to be very toxic, and that's going to be a significant GMP problem, right?
That's what he said in this e-mail, correct?
A. He said that; but, again, you know, he's not a toxicologist, right? And now we know, you know, based upon, you know, some of the FDA's training -- you know, training material, not all, you know, N-nitroso compound are, you know, as toxic, okay.
Quite a few of them, if you look at FDA's training, you know, PPTs there are quite of few N-nitroso compound that they are not, you know, not, you know, you know, you know, genotoxic, or they are not mutagenic.
So, again, you know, yeah, he's making, you know, you know, his own judgment, you know, outside of his, you know, you know, you know, expertise.
Q. He turned out to be correct, right? Because NDMA and NDEA are considered to be mutagenic/genotoxic impurities,

Page 102

correct?
MR. GALLAGHER: Objection.
Calls for speculation.
You can answer.
A. Yeah. Right now, yeah. And it's considered as probable, you know, you know, carcinogenic, you know, to human. But it's, you know, it's probable.
And also, again, based upon, you know, some recent FDA's training material, you know, I just went through as part of the preparation.
And endogenously formed NDMA could be, you know, somewhere between 1,000 or even greater than 2,000 microgram per day. You know, basically, you know, those NDMA, they -- you know, you know, you know, it is formed, you know, inside the body, like inside a human body, after, you know, ingestion, you know, of regular foods.
Q. NDMA was being formed by the manufacturing process, as we agreed earlier. It was a process impurity in the valsartan, correct?

Page 103

A. Yes.
Q. And it would never be acceptable to have NDMA at the levels it was found in your company's valsartan. That would never be acceptable, that could never, ever be permissible, correct?
MR. GALLAGHER: Objection.
Lacks foundation, and outside the scope.
A. Yeah, that's not accurate, okay? That's not accurate. If you look at FDA's -- you know, at least the most recent, you know, there is an acceptable limit for NDMA or NDEA, okay?
BY MR. SLATER:
Q. Are you aware that every single batch of valsartan manufactured with both the sodium nitrite quenching process with TEA and the zinc chloride process, that every single batch exceeded the FDA's stated limits?
Are you aware of that?
MR. GALLAGHER: Objection.
Outside the scope.
A. That's not accurate, okay? You

Page 104

know, as I indicated for the TEA process, you know, based upon my knowledge retrospectively, only very limited batch, you know, had NDMA exceeding, you know, the limit, as well as for -- I think for the -- for NDEA, there's also limited numbers.
So for the TEA process, as far as I can remember, the vast majority of the batches, they still met the acceptable -- the current acceptable limit, although those limits are retrospective.
BY MR. SLATER:
Q. The zinc chloride process, every single batch that was manufactured and then sold in the United States exceeded the limit set by the FDA, correct?
MR. GALLAGHER: Objection.
Outside the scope.
You can answer.
A. Okay, retrospectively, yes. But, you know, to be clear, you know, there was no specification before the events.
BY MR. SLATER:
Q. When Jinsheng Lin said at the

Page 105

end of this e-mail, "This indicates that other companies have paid attention to the quality problem very early on," when he was referring to the 2013 patent application, and then said, "So leaders please pay attention to this issue," he was giving you a good warning that this needed to be taken care of and fixed right away, because it was a serious quality problem with a very toxic substance, correct?
MR. GALLAGHER: Objection.
Vague, and mischaracterizes the document.
A. As I said, you know, you know, now looking back, you know, you know, he's making, you know, his judgment, okay.
Also, he's -- you know, particularly with regard to the potential toxicity of NDMA, because he's not a toxicologist.
BY MR. SLATER:
Q. Well, he was right that this was a quality problem and that it needed to be taken care of. That was a good decision

Page 106

by him to recommend to you and the other leaders to fix this problem, this quality problem, in 2017, right?

MR. GALLAGHER: Objection. Vague, and calls for speculation.

A. Again, as I said, you know, he's making, you know, you know, those guesses.

BY MR. SLATER:

Q. Whatever you want to call it, he was correct, right?

A. Again, you know, he's making those speculations outside of his, you know, expertise.

Q. Let's go to -- well, rephrase. Let me just tie this up.

When people outside ZHP found out what ZHP knew at least as of July 2017, and likely earlier, since he's talking about what was already known, when the rest of the world found out about it, you couldn't sell your valsartan anymore because of the contamination with the NDMA, correct?

MR. GALLAGHER: Objection.

Page 107

Vague, and outside the scope.

A. Again, you know, as I said, he's making his speculations.

BY MR. SLATER:

Q. Well, whatever you want to call it, he was correct that the sodium nitrite quenching was creating nitrosamines, which was a serious GMP problem, correct?

MR. GALLAGHER: Objection. Vague, and outside the scope.

You can answer.

A. In terms of a GMP, you know, Ms. Ge would be in a better position, you know, to answer that.

MR. SLATER: Let's go, Cheryll, if we could, to the patent application referred to here. Let's go to the English version.

(Whereupon, Exhibit Numbers ZHP-297 and ZHP-298 were marked for identification.)

BY MR. SLATER:

Q. We're just getting the document up. Great.

Page 108

So I can represent to you that on the metadata, this is the attachment referred to as the patent application. Do you see that? With an application announcement date of March 5, 2014 in the top right.

A. Yes.

MR. SLATER: And just for the record, Cheryll, could you scroll to the bottom, and we'll just read off the Bates number that is printed on this?

It says ZHP01812101.

Now, if you could scroll down a little more, Cheryll. Let's just get the abstract fully shown here. No, no, the other way. The other up. Perfect.

Q. Looking at the Abstract of this patent application, I want to go down to the last long sentence at the bottom, and it says starting six lines from the bottom, "In the method of the present invention, the use of hypochlorite can cut off the source of

Page 109

nitrous acid and eliminate the generation of valsartan impurity K, and, with the adjustment of other conditions, it can prevent the generation of other impurities that are difficult to handle, allowing the preparation of high-purity valsartan products."

Do you see that?

A. Mm-hmm.

Q. And per the e-mail that we just went through from Mr. Lin, he talked about how the people who filed this patent at this other company actually were looking at a way to prevent these nitrosamine impurities from forming by substituting something else for sodium nitrite.

Do you recall we just went through that?

A. Yes. But here, you know, you know, based upon what I see here, right, this patent is specifically, you know, talking about, you know, the impurity K, okay?

So retrospectively we know that, you know, the impurity K is an

Page 110

N-nitroso impurity, right, but that impurity, it looks like, you know, you know, Novartis, they already knew, right, during their initial filing. Okay. And also they did an Ames test of the so-called impurity K, and it turns out, you know, the Ames test results was negative, right?

So according to a European, you know, authority document, this impurity, you know, you know, has been controlled as a regular normal impurity, okay, at the level of 1,000 ppm.

Q. I guess we could talk about that for a moment.

You realize that whatever the results of the Ames test was, the regulatory authorities said it should be treated as a mutagenic genotoxic impurity, correct?

MR. GALLAGHER: Objection. Foundation, calls for speculation, and outside the scope.

You can answer.

A. According to M7, if the results of Ames test, if it's negative, you could

Page 111

control that or treat that as a regular impurity.

So in this particular case, impurity K has been treated by Novartis, which is the original innovator of valsartan as a regular impurity. So its level is at 1,000 ppm.

BY MR. SLATER:

Q. Let's look at -- well, rephrase.

You're aware that the regulatory authorities actually determined not to treat it as a regular impurity and said it had to be treated as a genotoxic impurity, correct?

MR. GALLAGHER: Objection.

A. Not for -- sorry.

MR. GALLAGHER: Go ahead. Outside the scope.

You can answer.

A. Yeah, not for impurity K. As I said, impurity K has been controlled as a regular impurity, although it is N-nitroso impurities.

Page 112

BY MR. SLATER:

Q. NDMA and NDEA are not treated as regular impurities; they're treated as what they are, potent genotoxic impurities, correct?

MR. GALLAGHER: Objection. Vague, and calls for speculation.

A. They are different. NDMA, you know, you know, you know, every N-nitroso compound, they are different. As I, you know, early -- you know, you know, early on, as I indicated, there are quite a few, you know, N-nitroso, you know, compounds, they are not mutagenic.

MR. SLATER: Hang on. Let's see where I want to go to now in this document.

Let's go to page 5, paragraph 17, please. No, we're way past it. Paragraph 17. I see what you're doing, actually. You're right. There you go. Perfect.

Q. Paragraph -- or Section -- rephrase.

Page 113

Section 17 is talking about -- well, actually, let's go -- yeah, all right. Rephrase.

In 17 it talks about, "In the present invention, the improvement of Step 3 reaction can effectively prevent valsartan impurity K from forming; since valsartan impurity K is a nitroso compound that is highly toxic, the control of impurity K in valsartan so that it is not detected is the objective of the valsartan preparation method of the present invention."

Do you see what I just read?

A. Yes.

MR. SLATER: Now let's go, if we could, to paragraph number 33.

Q. It says in paragraph 33, starting in the second sentence, "Through the control of the reaction conditions, the valsartan product is synthesized while the formation of other impurities is minimized, allowing effective control of the content of impurities, thereby preparing high-purity valsartan products, and enhancing their

Page 114

quality, which is of great significance for ensuring the safety of valsartan APIs."

Do you see that?

A. Mm-hmm.

Q. And you would certainly agree with me that if you could prevent the creation of nitrosamines by substituting something for sodium nitrite, that's good for safety, correct?

A. This is something unknown, and it's speculative. Because if you use other quenching, you know, reagent, you might create something new, some -- you know, some new problems, okay.

Q. That's why you test it and study it before you sell it on the market for patients to take it, right?

MR. GALLAGHER: Objection. Vague.

A. Yes. You will do the -- yeah, you will do the risk analysis. But based upon the claim, you know, you know, in this patent, you know, particularly with regard to impurity K, you know, they claim is highly

Page 115

toxic, but actually it is not based upon, you know, the knowledge that we know today.

BY MR. SLATER:

Q. Well, you're not saying NDMA and NDEA aren't toxic, because they're accepted to be highly toxic and unacceptable to be included in the API.

A. Well, I am -- the focus of this patent is, you know, is impurity K, okay. So anything, you know, you know, beyond that, you know, is their speculation, right?

And also, you know, they claim vitamin -- I'm sorry -- the impurity K, you know, is highly toxic, you know, based upon, you know, whatever, you know, available from either European regulatory, you know, you know, agency, I think this statement is not correct.

Q. We've confirmed as through the e-mail we went through from Mr. Lin earlier that your company had this patent in its files, correct?

A. You know, right. It looks like at least Mr. Lin has it. I don't know --

Page 116

yeah. Well, he sent it to other people. Yeah.

Q. And this would have been available to and would have been reviewed by your company most likely in 2014 when it was available to be seen, correct?

A. I don't know.

MR. GALLAGHER: Objection. Calls for speculation.

MR. SLATER: All right. Let's go to the next document. We can take this down. Cheryll, let's go to ZHP02336567.

(Whereupon, Exhibit Number ZHP-299 were marked for identification.)

BY MR. SLATER:

Q. Do you see that on the screen?

A. Mm-hmm.

Q. Okay. You see the title is "Valsartan Patent Investigation Report"? Is that a fair reading of that?

A. Yeah, it's accurate.

Q. And if you turn now to the next

Page 117

page -- and we didn't bring up the whole document for time's sake, but let's go to the second page of this document, which is page ZHP02336682.

You can see in the middle of the page the patent number of CN 103613558, which is the patent number that was on the patent we just looked at.

Do you see that?

A. Mm-hmm.

MR. GALLAGHER: I'm going to object to the extent this document -- it appears you're representing that this document is incomplete, so I'm just going to object to that extent.

But you can proceed with your questions.

MR. SLATER: What I'm representing is that we have the front for you, and we have this page, because that's what we wanted to talk about. But we certainly can provide you the entire document if you want at the break, if you want to go through

Page 118

it. We were just wanting to focus on this for time purposes.

MR. GALLAGHER: I'm just making clear for the record, you know, if your questions -- you're happy with an incomplete document.

MR. SLATER: Are you objecting to my use of the document in this form?

MR. GALLAGHER: I'm just noting an objection that the document is incomplete. I don't know what is in the rest of the document. If for your questions you feel like the cover page and this page is insufficient --

BY MR. SLATER:

Q. Okay. So looking now at the section we're talking about now, it says the title of the invention was "A Method for Preparing Valsartan," correct?

A. Yes.

Q. The applicant was Zhejiang Second Pharma Company, Limited, correct?

A. Yes.

Page 119

Q. And if you go down to the bottom so that we can cut to the chase, it says, "Patent infringement analysis. The Huahai process does not add sodium hypochlorite, so it does not constitute an infringement."

Do you see that?

A. Mm-hmm.

Q. And I can tell you from the metadata this document was last modified November 4, 2014, according to the document.

If that's what the metadata shows, you would expect that your company had access to and reviewed that patent in 2014, correct?

MR. GALLAGHER: Objection. Foundation, and compound.

A. It looks like this -- you know, you know, we have a patent group, okay, and it looks like this is a report generated, you know, by that patent, you know, group, okay.

And again, you know, this particular patent, the focus is related to impurity K. Okay. It didn't even -- yeah,

Page 120

looks like, you know, based upon the material that you just showed, you know, it just didn't specifically mention, you know, anything else. You know, it just vaguely say, you know, for all other or other impurities, but it just -- there is no specification, you know, specifics.

BY MR. SLATER:

Q. I'm just honestly trying to just establish the time period when it was reviewed.

A. Yeah, that's fine. Yeah, yeah, that's fine, yeah.

Q. Okay. So you could agree based on what I've told you this was reviewed likely in 2014 by someone in your company, correct?

MR. GALLAGHER: Objection. Foundation, and calls for speculation.

A. It looks like it.

MR. SLATER: I think we have -- Cheryll, do you have the second document also where this is referred to, the second ZHP document?

Page 121

We don't have to go to that, actually. We're going to go to the next document. Oh, you have it. Oh, you know what? You put it up. You're so quick, I can't waste that effort.

(Whereupon, Exhibit Number ZHP-300 was marked for identification.)

BY MR. SLATER:

Q. On the screen is ZHP02336432, which is a summary of patents for a patent search. And I can tell you based on the metadata this was modified May 23, 2014.

That's what the metadata shows, okay?

A. Okay.

Q. And if we go to the second page of this document, the bottom of the page, number 4, you can see that this is a discussion of the same patent you see that we've been talking about.

Do you see that? Same number, CN 103613558. Do you see that?

A. Where? I'm sorry. Where

Page 122

exactly the number?
Q. Right in the middle of the page. I mean right in the middle of the "From" section.
A. Oh, yeah, yeah, yeah. Okay, yeah. I saw that, mm-hmm.
Q. And this document, which was compiled in 2014 within ZHP, at the very end of that description says, "The method inhibits the generation of valsartan impurity K and other impurities hard to treat, so as to yield high-purity valsartan."
Do you see that?
MR. GALLAGHER: Objection. Foundation, and calls for speculation.
A. I'm sorry, where the language?
BY MR. SLATER:
Q. The last sentence.
A. Last sentence, "and other impurities hard to treat so as to" -- okay, yeah.
Q. So at the very least, ZHP was aware, at least as of 2014, that there were other companies out there trying to eliminate

Page 123

the quality problem created by having nitrosamines yielded through sodium nitrite quenching.
Your company would have been aware that others were doing that, correct?
MR. GALLAGHER: Objection. Foundation, and mischaracterizes the document and the testimony.
A. It looks like somebody in the company, yeah, aware of this patent. But again, you know, this patent, as I said, is focused on impurity K.
MR. SLATER: All right. The next document I have is probably going to take a little while, and I think I've been going about an hour. I'm happy to keep going. I'm going to need 15, 20 minutes at least for the next document. So you tell me, Patrick.
MR. GALLAGHER: Dr. Li, it's really up to you. Do you want to take a break now, or do you want to go for another 15 minutes?

Page 124

MR. SLATER: We can take a break now, yes.
Go off the record then.
THE VIDEOGRAPHER: The time right now is 9:24 a.m., and we're off the record.
(Whereupon, a recess was taken.)
(Whereupon, Exhibit Number ZHP-301 was marked for identification.)
THE VIDEOGRAPHER: The time right now is 9:43 a.m. We're back on the record.
BY MR. SLATER:
Q. On the screen we have Exhibit 301, an e-mail from December 22, 2018.
Do you see that?
A. Yes, mm-hmm.
MR. GALLAGHER: Adam, is there an English language version of this document?
MR. SLATER: That's a good

Page 125

question. I don't know.
Let's go off for a second. If there isn't, we'll create one right now.
THE VIDEOGRAPHER: Off the record?
MR. SLATER: Yes.
THE VIDEOGRAPHER: The time right now is 9:44 a.m. We're off the record.
(Off the record discussion.)
(Whereupon, Exhibit Number ZHP-302 was marked for identification.)
THE VIDEOGRAPHER: The time right now is 9:44 a.m. We're back on the record.
BY MR. SLATER:
Q. Looking now at this e-mail -- rephrase.
Looking at Exhibit 301, it's an e-mail that was sent to you and a few other people on December 22, 2018, is that correct?
A. Yes.

Q. Who was the e-mail written by?
A. Also from Mr. Lin.
Q. The same person who wrote that e-mail of July 27, 2017 that we went through earlier?
A. Mm-hmm.
Q. And he writes to yourself, and who else is copied? Who else was this written to?
A. Mr., you know, Zhu and Chen, Chen Wenbin, yeah.
Q. Who are those people? Let's take them one at a time, if you could, please.
A. These two, Mr. Zhu and also Mr. Chen, Mr. Zhu is actually my direct report.
Q. He reports to you?
A. Yes.
Q. What's his title?
A. He is -- the title is the director for CEMAT, yeah. Analytical -- yeah.
Q. I'm sorry. You said

"analytical" --
A. It should be director of analytical chemistry or something like that, or just, you know, director of analysis, yeah. In Chinese we call (speaking Chinese).
Q. And the other person, Mr. Chen, who is that?
A. He is under Mr. Zhu. He is the associate -- yeah, should be the associate director, yeah.
Q. And tell me if I understand what this e-mail is saying. It has -- first of all, it has an attachment, which we're going to get to in a moment.
It is a summary of CEMAT projects with a long report review cycle.
Do I understand that?
A. Right. Right.
Q. The e-mail reads -- rephrase.
The e-mail reads, "Mr. Li: Attached please find the summary of 27 recent projects with a report review cycle of more than two months, including 16 impurity studies, one solid-state analysis, three

structural confirmations, and seven genotoxicity assessments. I hope to communicate with you and find a way to shorten the report review cycle, thank you."
Did I read that in a fairly accurate way?
A. Yes.
Q. And it was signed by Jinsheng Lin at CEMAT, December 22, 2018, correct?
A. Yes.
MR. SLATER: Let's now go to the attachment, which is the summary of the CEMAT projects with a long report review cycle.
THE WITNESS: Okay.
MR. SLATER: And that will be Exhibit 302.
THE STENOGRAPHER: I think it's 303. 302 was the English version. 303.
MR. SLATER: Thank you.
(Whereupon, Exhibit Number ZHP-303 was marked for identification.)

A. Could you enlarge? It's really difficult to see from my end.
BY MR. SLATER:
Q. We're going to when we scroll up to it.
MR. SLATER: But I also -- Patrick, if you'd like, I think we have an English version of this machine translated, is that correct?
MR. GALLAGHER: That would be awesome if you do.
MR. SLATER: So we'll load that up before I ask any questions.
Let me know, Cheryll, when it's been loaded.
MR. GALLAGHER: There it is. You're good to go.
(Whereupon, Exhibit Number ZHP-304 was marked for identification.)
MR. SLATER: So looking now at this spreadsheet, let's go, if we could, to Tab 1.3, Row 53. Perfect. Scroll down a millimeter. Do we have

Page 130

the top of 53?
Sorry, I shouldn't have made you do it.
A. Go the other way. Could you make it bigger?
BY MR. SLATER:
Q. We'll make it bigger and work our way down?
A. Could you make it even bigger?
MS. CALDERON: Give me one second. I'm working on it.
THE WITNESS: Okay.
MR. SLATER: Just make it bigger and then we'll scroll through it as we go, so you don't have to try to fit the whole thing on one page. Make it nice and big. There we go.
MS. CALDERON: Sorry.
MR. SLATER: Don't worry about it. No one else can do it.
MS. CALDERON: Obviously I can't either.
MR. SLATER: Keep going. You got it. You're going slowly down.

Page 131

Now you're at 172 again.
MS. CALDERON: That's it.
MR. SLATER: Thank you.
BY MR. SLATER:
Q. Okay. Looking now in Box 53, at the top it talks about Investigation on the RT 26-minute impurity in irbesartan crude product.
Do you see that?
A. Mm-hmm.
Q. It says the responsible person was Tianpei Huang, new project in July 2017, completed in April and no longer updated in May.
Do you see that?
A. Mm-hmm.
Q. And again, who is Mr. Huang?
A. She is one of the analysts at the time.
Q. She was an analyst at CEMAT?
A. Yes. She was, actually.
Q. It says, "The project was authorized by the Technology Department of Chuannan in Plant 1."

Page 132

Do you see that?
A. I'm sorry, where?
Q. Where we just read. It says, "The project was authorized by the technology department of Chuannan in Plant 1."
A. Which line?
Q. Right after I just read about "no longer updated in May" in red.
A. Wait a second. Oh, the red, okay. Yeah. Yeah, they actually, yeah, ask CEMAT to do the investigation, yes.
Q. So how does that work? You have Chuannan and Xunqiao, if I'm pronouncing those right, if they have something like an impurity investigation they need to do, they ask CEMAT to do that work for them?
A. Well, sometimes they will do by themself along with, you know, Chuannan QC. But if they cannot resolve, yeah, they usually send it to us.
Q. And then I'm going to read a little further. It says, "Due to the incomplete quenching of sodium azide caused by the separate treatment of irbesartan

Page 133

sodium azide wastewater, there is a frequent occurrence of muffled explosion in the production process, so the technology department carried out the technical improvement by which the sodium azide quenching takes place in the unstratified step in the crude irbesartan process."
Do I have that correct?
MR. GALLAGHER: I'm going to object to this as outside the scope.
But please answer to the extent you know and can.
A. Yeah.
BY MR. SLATER:
Q. It then continues -- and, by the way, when it talks about the "unstratified step in the crude irbesartan process," what does that refer to, "unstratified," in that context?
A. Unstratified. I'm sorry, I don't understand exactly what you mean by "unstratified."
Q. Well, I'll ask the question differently then. Let me just continue.

Page 134

It continues, "However, after the improvement there is an unknown impurity of about 0.5 percent at 26 minutes in the crude irbesartan, and the structure of this impurity needs to be investigated."

Do you see that?

MR. GALLAGHER: Again, I'm going to object as outside the scope.

But please answer to the extent you know and can.

A. So could you point out exactly, like, which line? I'm sorry. Because, you know, the English and the Chinese, you know, version --

BY MR. SLATER:

Q. Can I point out exactly what line? I'm not going to be able to point out exactly what line. How about this is all above the "July Process Update."

Do you see that?

A. Let me -- how about let me -- you know, let me take a little bit of time and read this through, okay?

Q. Sure. Let's go off the timer,

Page 135

and you can take a look, and then we'll walk through it a little more generally. That's a good idea?

A. Okay.

MR. SLATER: Stay on the record, off the clock. No problem.

(Witness reviewing document.)

THE WITNESS: Okay. I basically read through. We can go ahead.

BY MR. SLATER:

Q. I'll start over.

In this Box 53, you can see there's a discussion of the investigation of the impurity in the irbesartan crude product that we were talking about per that prior e-mail that Jinsheng Lin wrote, correct?

MR. GALLAGHER: I'm going to object to the questioning about this box as outside the scope so I don't have to keep repeating it.

MR. SLATER: That's fine. You've got that objection.

///

Page 136

BY MR. SLATER:

Q. And you said "correct," right, Dr. Li?

A. I'm sorry, say that again?

Q. What they're discussing in this Box 53 is a study, a research project that was being performed that followed from that e-mail that Jinsheng Lin wrote that we talked about a few minutes earlier, correct?

A. It looks like.

Q. Then there's process updates going forward. And it shows, for example, in July, in part it says that "Based on the process of generation, the impurity should be a nitroso compound in irbesartan. The degradation experiment is currently being carried out, and subsequently the sample will be prepared."

That's correct in part, right?

A. Mm-hmm.

Q. And when they refer to "a nitroso compound," we're talking about a nitrosamine, correct?

A. This nitrosamine is the nitroso

Page 137

compound on the irbesartan, okay. It's very specific.

Q. Then there's an August process update in August 2017 that said, "The forced degradation experiment proved that the impurity was a result of the reaction of irbesartan with sodium nitrite and hydrochloric acid. At present, the impurity has been prepared by thin layer chromatography."

Do I have that correct?

A. Yes.

Q. Then in September there's a process update that says, "The impurity standard production has been separated and was sent to Dan Li for nuclear magnetic resonance."

My first question is, who is Dan Li?

A. She is a person specializing in NMR structure characterization, or nuclear magnetic resonance.

Q. And what's the purpose of that test in this context? What would that be

Page 138

trying to show?
A. Trying to elucidate, you know, the structure.
Q. The structure of the nitrosamine?
A. No, that particular, you know, nitroso compound with irbesartan.
Q. And then it points out that there was a malfunction of the equipment so the test couldn't start at that time.
Do I have that right?
A. Yes.
Q. And then if we go forward, there are updates in October and November, and then in December it says the research report is being completed, correct?
A. Yes.
Q. And then in January, now January 2018, it says that the research report was completed pending review, correct?
A. Correct.
Q. Then we go forward into March. There's no update in March, right? Just says, "No update"?

Page 139

A. Right.
Q. And then in April it says, "After discussing with Mr. Li, as the project involves an impurity that is sensitive so no research report will be issued and no further updates will be made." Correct?
A. It looks like so.
Q. So you instructed that this research project not go forward any further and no report to be issued, as documented here, correct?
MR. GALLAGHER: Objection. Foundation, and assumes facts.
BY MR. SLATER:
Q. That is what it says, correct?
A. Based upon what it says, yeah, it looks like so.
Q. Do you know where that report is?
A. I don't recall.
Q. Where would we look to find that report? Because I can represent we've been looking for it and have been unable to find it.

Page 140

Do you have any idea where we would look to find that report?
A. I don't -- I don't recall. You know, I don't even recall this particular discussion. I mean, you know, this so long, you know, you can see there's so many projects, you know, ongoing. So I really don't, you know, remember the specifics.
Q. And, again, this says that the reason why the research report was not to be issued and not to be updated any further was after discussing with you, you had pointed out that the project involves an impurity that is sensitive.
That's what the document shows, correct?
A. It looks like so.
Q. And reading that doesn't refresh your recollection of telling your team to -- not to do anything further with the report and not to issue it? You don't recall that?
A. As I said, I don't remember, you know, the specifics. Maybe the reason

Page 141

is, you know, you know, I can -- maybe the reason is basically this is not, you know, relevant to a real process, right? Because this is a trial and, you know, they -- you know, during the trial they change the way of the -- you know, of the quenching, right?
So, yeah, so basically, you know, you know, this compound would not be present in a normal registered, you know, the process.
So maybe I want to just, you know, ask them to -- because issuing this could be -- could have caused some confusion. You know, people may confuse the presence of this particular impurity with the registered, you know, process.
Q. You testified a few moments ago you don't recall this at all. So everything you're telling me about what might have happened --
A. This is what I'm trying to -- you know, it's a -- you know, what I'm trying to, you know, you know, reconfigure, you know, a possible scenario. You know, this is

Page 142

not, you know, you know, what really may happen. You know what I'm saying? It's just, you know, give some, you know, speculation, you know what I'm saying?

But, yeah, definitely I don't remember exactly, you know, what I had said during that particular time. Okay?

Q. Well, this document certainly sets forth that you were concerned at the time that the impurity was a sensitive impurity, and that would be talking about a nitrosamine impurity; that you were concerned about that, right?

A. Well, as I said, you know, you know, the possible reason, right? As I said, it's a possible reason.

You know, maybe I wanted to avoid, you know, the confusion of an impurity, you know, from this trial, you know, process, with an impurity from the real ones. Okay.

But again, look at this particular, you know, impurity, you know, this particular impurity itself, you know, if

Page 143

you look at a structure, it's not a typical N-nitroso compound, okay?

And based upon everything that we have know, you know, for now, you know, you know, if we were to do an Ames test on this particular, you know, nitroso compound of irbesartan, I would say, you know, you know, you know, a reasonable projection was -- you know, would be the Ames would very be likely be negative, okay, you know, based upon everything, you know, that we know by now, you know, based upon what they call a QSAR, quantitative structure-activity analysis.

You know, I mean, it's the same thing like impurity K, right? Because, you know, see, the reason is why those compounds may be Ames negative is because you have to -- you know, when you look at the activity of a compound, you know, one of the things you also have to look at is the serial chemistry, right?

So based upon the knowledge that we have, you know, gained, you know, up

Page 144

to now, you know, for those, you know, like large molecule and nitroso compound, particularly with substituents surrounding the, you know, nitroso compound, if they are big, typically you tend to have this kind of a, you know, nitroso compound to be Ames negative.

Q. At this time, as documented -- well, rephrase. I want to just go over a couple of basic facts that we have here, okay?

A. Mm-hmm.

Q. One of the things we know is that this demonstrates, as did the e-mail we went through before, that ZHP was aware that the sodium nitrite quenching was creating nitrosamine impurities. That you knew.

A. We knew based upon this document --

MR. GALLAGHER: Objection. Misstates the testimony.

Go ahead. Go ahead.

A. I'm sorry.

Based upon document, yeah, we

Page 145

knew specifically the nitroso compound of irbesartan, okay. And also, irbesartan is the main ingredient of that particular reaction.

Q. And you also knew per the e-mail we went through that NDMA occurs in valsartan when it was quenched with sodium nitrite. That was known as of July 2017. That's why that was stated by Jen Sheng Lin, correct?

MR. GALLAGHER: Objection. Mischaracterizes.

A. As I told you, you know, you know, for that e-mail, you know, I do not recall. Now looking back, you know, you know, basically, as I said, anything about, you know, you know, valsartan is huge speculation because, you know, you know, the data that's shown here is specifically regarding to irbesartan.

BY MR. SLATER:

Q. Well, why don't we do this. Let's just -- in fairness, let's go back to the e-mail to get ourselves oriented here.

Page 146

A. Okay.
Q. And that was Exhibit -- gosh, I lost track of which exhibit it was. Cheryll knows. She's going to find it.
MS. CALDERON: Do you want me to put it up?
MR. SLATER: I would, please.
And if we can clarify for the record what exhibit number that was, I'll write it on here so I won't forget again.
MS. CALDERON: Hang on one second. It's 295.
MR. SLATER: Great. Thank you. And let's go to the top of the second page again. Just -- okay.
Q. Looking now at the top of the second page of Exhibit 295, which was an e-mail dated July 27, 2017, from Jinsheng Lin in your CEMAT facility, he pointed out that what was being seen with the irbesartan is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite.
That's part of what Jinsheng

Page 147

Lin said in that e-mail, correct?
A. Well, in his -- see, in the beginning of the sentence, he said, you know, it's likely, you know, or most likely, right? So -- yeah, so that's a speculation.
BY MR. SLATER:
Q. Well, actually, let's walk through it then.
What he said was, "Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO compound."
That's talking about what's being seen in the irbesartan, correct?
A. Yes.
Q. Then after the semicolon he states, "It is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite," correct?
MR. GALLAGHER: Objection. Mischaracterizes.
BY MR. SLATER:
Q. That's what it says, right?

Page 148

MR. GALLAGHER: I guess I want to clarify. Are you looking at the English language translation, or are you looking at the actual Chinese language document?
MR. SLATER: Well, I don't know why that matters, honestly. You have them.
MR. GALLAGHER: I don't see any semicolons in the Chinese language document.
THE WITNESS: Yeah, in the Chinese language, it's just a regular comma. Yeah, it's a comma.
MR. SLATER: Okay. There's a semicolon objection. I'm going to fix it. I'll start a new question.
BY MR. SLATER:
Q. After pointing out what we just established had to do with irbesartan, Mr. Lin then says, "It is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite."
That's what he says in this

Page 149

document July 27, 2017, correct?
A. Yes.
Q. Do you know how long your company knew that NDMA occurs in valsartan when quenched with sodium nitrite, how long before July of 2017 people in your company knew that?
A. I don't know. Looks like only he knows at the time.
Q. He was the one who did the patent review, right, that we went through before, going back to 2014 on this, right?
A. Mm-hmm.
Q. So at least this person who you told us was a, and remains an important person in your organization was looking at this issue going back to 2014. We've established that with the document, correct?
MR. GALLAGHER: Objection. Mischaracterizes the testimony.
But please answer.
A. Yes.
BY MR. SLATER:
Q. And we also know that he was

Page 150

concerned -- rephrase.
And we also know that he was concerned --
MR. SLATER: If we scroll down to the second-to-last paragraph on this page.
Q. -- that with regard to the irbesartan, if it was in a nitrosamine compound, "then its toxicity will be very strong, and there will be an extremely high GMP risk."
That's what he says, right?
MR. GALLAGHER: Objection. Outside the scope.
A. Again, as I said, you know, he's making speculation outside of his expertise.
BY MR. SLATER:
Q. Well, what he's doing is analyzing what we know from earlier testimony you gave was the root cause for the NDMA formation which was caused by the sodium nitrite, correct?
A. Part of the -- yes.

Page 151

Q. So he was correct that the sodium nitrite quenching creating nitrosamines was a serious GMP problem.
He was correct about that, right?
MR. GALLAGHER: Objection.
A. That's speculation.
BY MR. SLATER:
Q. Well, if you want to call it speculation, that's fine. But it was confirmed, and that's the root cause analysis that you've already testified to that your company came to, right?
A. After, you know -- yeah, after the events, yes.
Q. Well, that's what was disclosed after the events, but this e-mail shows that people in your company knew about this, including yourself when you got this e-mail, in July of 2017, right?
A. As I said, you know, you know, I am -- you know, I was under this, but I -- you know, as I said, I didn't have time to, you know, go through everything and, you

Page 152

know, I don't recall, you know, specifically looking through this e-mail.
Q. And, in fact, the right thing to do at this point when you're -- rephrase.
The right thing to do -- as soon as your company knew that nitrosamines were being yielded by the sodium nitrite quenching, the right thing to do would have been to stop production and optimize the process at that time and reveal to world regulatory authorities this problem, right?
That would have been the right thing to do when your company discovered this internally, right?
MR. GALLAGHER: Objection. Vague, outside the scope, and calls for speculation.
A. You know, I don't know, or I didn't know at the time how far, you know, you know, this went through, right.
He sent to those people. I didn't know, and I do not know, you know, how those people -- their response. They may ignore or they may think this -- you know,

Page 153

maybe he's -- Mr. Lin's speculation.
So, basically, it looks like it didn't, you know, go far.
BY MR. SLATER:
Q. In retrospect, it's too bad it didn't go far because the right thing to do would have been to disclose this to the regulatory authorities and stop production, right?
MR. GALLAGHER: Objection. Vague, outside the scope, calls for speculation, and asked and answered.
THE WITNESS: I mean, do I need to answer?
MR. GALLAGHER: Answer to the extent -- you know, to the extent you can.
THE WITNESS: Sure.
I mean basically, you know, for me it's the same thing. I mean, retrospectively, you know, you know, it might be, but at the time people may thought, you know, he just, you know, making his speculations and --

Page 154

BY MR. SLATER:
Q. Well, looking at the last sentence, he said -- rephrase.
Looking at the last paragraph, he said in part, after looking at the patent going back to 2013 and 2014 from one of your competitors, that that indicated that other companies had paid attention to the quality problem very early on, and that quality problem is sodium nitrite quenching creating nitrosamines in your company's sartans, including valsartan, correct?
That's what we've established, correct?
A. Well, again --
MR. GALLAGHER: Objection. Mischaracterizes the testimony and the documents.
A. Right. I mean, you know, once again, that N-nitroso compound, right, specified in the patent, you know, was, you know, impurity K, okay.
So this impurity K, as I said, has been controlled as a regular impurity,

Page 155

okay? Its level is 1,000 ppm.
BY MR. SLATER:
Q. Is that what you believe the FDA permitted your company -- rephrase.
Is that your understanding of the FDA's position on that impurity?
MR. GALLAGHER: Objection. Outside the scope.
THE WITNESS: I'm sorry. Go ahead.
MR. GALLAGHER: Objection. Outside the scope.
To the extent you know, please answer.
A. Okay. I mean, FDA is well aware of the impurity K is Ames negative, okay.
BY MR. SLATER:
Q. I'm just asking, do you know what the FDA's position was on the impurity K? Do you know whether they thought it could be handled as a regular impurity or whether they said it had to be limited to 0.3 ppm?
Do you know?

Page 156

MR. GALLAGHER: Objection. Outside the scope.
To the extent you know personally, you can answer.
A. I do not know what FDA's, you know, you know, specific requirement at this time, okay? But in one of the communications I think came, you know, from FDA last year, they asked us to do some further in vivo animal study on the impurity K, okay, which we did.
We did a particular in vivo, you know, enrolled in animal studies according to the principle of, you know, ICH M7, and we submitted this, you know, you know, proposal back to FDA.
I think our proposal was to -- you know, essentially there is no need to control at such low level. It would be controlled, you know, based upon our current, you know, process.
I don't remember exactly, you know, what specific, you know, specification that we'd propose. It could be like several

Page 157

hundredths of ppm.
BY MR. SLATER:
Q. Let's be clear. You're talking about impurity K, right?
A. Right.
Q. You're not talking about NDMA or NDEA, right?
A. No.
Q. Because those would never be acceptable at regular levels, right?
A. Retrospectively we know, yes.
Q. And you knew that the FDA guidances and the European guidances all said that nitrosamine compounds needed to be excepted from the threshold approach because they're considered so dangerous, they couldn't even be allowed to be included based on the standard threshold approach.
Were you aware of that?
MR. GALLAGHER: Objection. Outside the scope, and lack of foundation.
A. Retrospectively, based upon M7, yeah. That's in general. But as I said, you

Page 158

know, the European, you know, authority, they specifically had a discussion on impurity K, you know, in which obviously that's after, you know, these events came out.

And they specifically, you know, you know, at the time at least they allow the original -- it looks like the original Novartis specification at 1,000 ppm.

BY MR. SLATER:

Q. Let's come back now to this e-mail where I was reading with you, where Jinsheng Lin said, "This indicates that other companies have paid attention to the quality problem very early on."

Just to be clear, the quality problem was sodium nitrite quenching creating nitrosamines, correct?

A. Again, as I said, he's making speculations, and that pattern is specifically talking about impurity K.

Q. Well, he also talked above about NDMA forming in valsartan when it's quenched with sodium nitrite. He also pointed out that your company knew that as

Page 159

well.

He talked about that, right?

A. He talked about only he knew. I don't know anybody else at that time, you know, before his e-mail.

Q. When -- well, rephrase.

When you and Peng Dong and Linda Lin and the others in that e-mail got this e-mail, if that was the first time that you saw that, shouldn't that have been an alarm bell going off in your head and say, "My gosh, there's NDMA forming in our valsartan; this is a major problem"?

That would have been the appropriate response, right?

MR. GALLAGHER: Objection. Vague.

A. I mean, retrospectively, you know, you know, if I went through or if Mr. Lin specifically came to me, you know, that might be, you know, the starting of the, you know, of the action time.

But as again, you know, it looks like this e-mail just slipped through

Page 160

from my sight.

BY MR. SLATER:

Q. And slipped through Linda Lin's sight and Peng Dong? All of those, none of them did anything?

A. That, I don't know. I -- you know, I have no knowledge, you know.

Q. Do you know why it is that this e-mail, which was sent to Ms. Ge and to Peng Dong and Linda Lin, that it didn't show up in any of their custodial files, and none of them are listed as duplicate custodians on this document?

Do you know why that happened?

MR. GALLAGHER: Objection.

A. I don't know.

MR. GALLAGHER: Outside the scope.

BY MR. SLATER:

Q. You don't know?

Do you know why the report that's referenced in the spreadsheet that we went through that documents in April of 2018 you said, "The report will not be issued and

Page 161

it shouldn't be updated any further due to the sensitivity of this impurity," do you know why that report has never been produced to us?

MR. GALLAGHER: Objection. Outside the scope.

A. I have no idea.

BY MR. SLATER:

Q. One way to try to get that would be to search the custodial files of Dan Li and Tianpei Huang. They might have it in their custodial files, correct?

MR. GALLAGHER: I'm going to object to these questions as argumentative, they're so far outside the scope.

Why you would ask Mr. Li about searching documents of other people makes absolutely no sense.

So, you know, Dr. Li, you can answer to the extent you have any knowledge of this.

But, Adam, I think you need to move on.

Page 162

MR. SLATER: Well, these people work for him, and he knows where they keep their documents and how they keep their files.

MR. GALLAGHER: Those aren't the questions you're asking.

A. They are the first-line analysts, okay, and they usually -- you know, they don't talk to me, you know, very often, you know, at my level.

BY MR. SLATER:

Q. If that report was destroyed, would that be acceptable in terms of how your department operates?

A. I don't know whether it's been destroyed or not.

Q. If it was destroyed, would that be acceptable?

A. That's a hypothetical question. It may be destroyed or, you know, per company's -- you know, because everyone, you know, company has certain -- as I mentioned, you know, you know, on the company server, if you deleted something, you know, because from

Page 163

time to time your mailbox fill up, and some people, you know, you know, they have -- may have to have it to, you know, very often to delete it, right?

So after, you know, certain period of the deletion it will be automatically, you know, like, taken from, you know, the company server.

Q. Let's also talk about -- well, rephrase.

We talked about the patent, and you spoke about impurity K a bunch of times.

A. Mm-hmm.

Q. A very important message in these e-mail and in that patent is that it was figured out, your company knew it and others started to figure it out on the outside, that the way to avoid creating nitrosamine compounds was to not quench with sodium nitrite.

That's an important lesson that's being discussed here, right?

MR. GALLAGHER: Objection. Mischaracterizes the testimony and the

Page 164

documents.

BY MR. SLATER:

Q. I'll ask it -- there's an objection. Let me ask a different question, because there's an objection. So I'm going to strive for a better question.

The -- rephrase.

Knowing that sodium nitrite quenching in the manufacture of valsartan was an important part of causing nitrosamines to be formed, that was important information, right?

MR. GALLAGHER: Objection. Vague.

You can answer.

A. You know, again, that patent specifically talking about impurity K, okay. Anything else, there is no specifics.

BY MR. SLATER:

Q. Well, what it talks -- rephrase.

The patent talks about how to avoid creating nitroso compounds. And that's the way you avoid it, is by not quenching

Page 165

with sodium nitrite, correct?

A. Again, as I mentioned, every nitroso compound, you know, is different, okay, specifically for the impurity K. Now we know, you know, it's, again, Ames negative.

So, you know, so do not confuse or replace that, you know, nitroso compound with NDMA.

I mean, you know, in that patent, as far as, you know, based upon the information that you presented, you know, I don't see so far, you know, in that patent, there's any specific mention of NDMA in that patent.

Q. No. What there's mention of is that your competitor wanted to eliminate sodium nitrite as the quenching agent and instead used bleach so that it wouldn't form nitrosamines as part of the process, correct?

A. I mean, again, you know --

MR. GALLAGHER: Objection.

A. -- that nitrosamine is not NDMA, okay, is impurity K. So, you know,

Page 166

okay, they are different.
BY MR. SLATER:
Q. At the very bottom of this page, which is, I think, where we went off on this tangent, but let me bring it back and then we'll move on.
At the bottom of this page Jinsheng Lin said, "This indicates that other companies have paid attention to the quality problem very early on. So leaders please pay attention to this issue."
That was a warning that you said either slipped through the cracks or was ignored, but it's a warning that should have been listened to, right?
MR. GALLAGHER: Objection. Mischaracterizes the testimony, and mischaracterizes the documents.
A. I think I already, you know, you know, answered your question before.
BY MR. SLATER:
Q. Well, in retrospect, you would agree with me that whenever the company knew at some point before July of 2017 that NDMA

Page 167

was occurring in valsartan when quenched with sodium nitrite, you would agree that as soon as that was known, action should have been taken to stop manufacturing by that process until it could be optimized to prevent NDMA from being created, correct?
MR. GALLAGHER: Objection. Vague, calls for speculation, and outside the scope.
A. Again, I think I already, you know, answered your question before. I mean, if you wanted me to repeat, you know, I mean...
BY MR. SLATER:
Q. Well, I'm just asking you simply, would you acknowledge sitting here now -- I'll ask it differently.
Do you wish when Jinsheng Lin sent this e-mail in July of 2017 that it hadn't been ignored and it didn't fall through the cracks, and that your company had taken immediate action to stop manufacturing valsartan with sodium nitrite quenching?
MR. GALLAGHER: Objection.

Page 168

Vague, calls for speculation, and outside the scope.
A. I mean, at a time of point, if someone went through, you know, and if they are like process, you know, people, they probably, you know, as I said, you know, just saw him, you know, just making unrealistic projections. That's my guess. That's my guess.
BY MR. SLATER:
Q. Well, you're calling it an unrealistic projection. In fact, he was 100 percent right.
A. No, he is not 100 percent right. As I said, you know, he's making, you know, those things -- as I said, you know, not everything -- by now we know not every nitrosamine is highly toxic, okay?
Like impurity K, based upon, you know, everything that we now know, you know, it has been controlled but treated as a regular impurity at 1,000 ppm, you know, that was by Novartis, the original inventor of valsartan.

Page 169

Q. You're certainly not telling me that valsartan with NDMA is acceptable to be sold with 1,000 ppm.
You're not saying that, are you?
A. I'm saying --
MR. GALLAGHER: Objection. Mischaracterizes.
THE WITNESS: I'm sorry again.
I'm saying since the beginning impurity K, which is also a nitrosamine compound, okay, right, the impurity K has been allowed by Novartis as well as by regulatory agencies, okay, at 1,000 ppm since the very beginning.
BY MR. SLATER:
Q. Didn't we establish a little earlier that you don't know what the FDA decision was with regard to impurity K?
A. I told you that --
MR. GALLAGHER: Objection. Outside the scope, asked and answered.
A. I told you I don't know what's

Page 170

the current FDA position. But I told you, you know, based upon a European regulatory agency's, you know, a document, right, after, you know, these events, they specifically discussed, you know, impurity K.

So based upon the knowledge from there, you know, that's how we came to know the impurity K has been, you know, at least, you know, towards that point, being controlled by Novartis at 1,000 ppm.

BY MR. SLATER:

Q. Okay. I'm asking about NDMA now. You understand that, right?

A. If you want to talk, yeah, we can talk now.

Q. It would never be acceptable to sell valsartan contaminated with NDMA, right? That would never be acceptable, right?

MR. GALLAGHER: Objection. Vague, outside the scope, and calls for speculation.

A. You know, I'm not a toxicologist, okay? So if you really want me to answer this question, I may give you my

Page 171

personal, you know, limited understanding by going through, you know, you know, the documents released by FDA particularly, some very recent, you know, training documents by FDA, right?

So, I mean, for a reliable intake on the specification for NDMA, even from the perspective of FDA, they have changed quite a bit, okay?

At the very beginning after, you know, you know, these events, FDA's position for NDMA was it should be absent. Okay. So basically, you know, you know, the specification would be defined by the limit of detection of a particular, you know, analytical method.

But then, you know, after I don't know how long, maybe about a year or so, FDA, you know, then said that, you know, after all of the understanding, you know, of the new knowledge, you know, now they allow, you know, it to be present like 96 nanogram per day, right, for, you know, valsartan.

And also if you look through

Page 172

some of the most recent training, FDA's, you know, like training, you know, you know, you know, training slides, it -- you know, you know, it mentioned that, you know, as I said earlier, you know, endogenously formed NDMA could be, you know, anywhere from 1,000 to more than 2,000 microgram per day. So this is, you know, extremely high. I mean...

So basically, you know, without taking any medication, anyone will have that much of NDMA in you and me and everybody else's body, okay, 1,000 to more than 2,000 microgram per day. This is from the official FDA's, you know, you know, training documents.

So basically our understanding with regard to, you know, you know, the potential toxicity of NDMA, it looks like it's still progressing.

BY MR. SLATER:

Q. The FDA is not permitting ZHP to sell valsartan with NDMA impurity in the United States even up until the present day, correct?

Page 173

MR. GALLAGHER: Objection. Outside of the scope.

BY MR. SLATER:

Q. Correct statement, right?

A. At this point, you know, the import ban is still there, but there's a lot of reasons. I think partly because of the pandemic.

We had a meeting with FDA, I think at the end of 2019. During that meeting, you know, FDA has pretty much, you know, accepted our explanation, our responses, and the consensus was they would come over early 2020 to come over on site to do like, you know, a follow-up inspection.

Q. The fact stands that from the time the FDA learned about NDMA in valsartan, they told ZHP to stop selling it and recall it, right?

A. The only --

MR. GALLAGHER: Objection. Outside the scope, and mischaracterizes, lack of foundation.

Go ahead.

Page 174

THE WITNESS: Yeah, sorry. Yeah.

I mean, only after certain period, you know, of the investigation, you know, and then, you know, FDA had the warning letter and also the import ban.

And, you know, once we confirmed, you know, the presence of NDMA, you know, in valsartan, we reported it to the FDA, and we give FDA our methods, and also we give FDA our testing results, right, only like maybe like two, three weeks, you know, after June 6th.

And we had been talking to FDA, asking for their guidance as to what we should do, right? Whether we should -- to do the recall, you know, immediately or whatever.

But, you know, I think, you know, during some of the early response from FDA, you know, FDA still at the time wasn't sure how to -- you

Page 175

know, how to move forward. They specifically asked us to hold on, you know, you know, to any recall, you know, that we would like to do.

BY MR. SLATER:

Q. You spoke to the FDA, right?

A. Yeah, yeah. I was in the meeting with FDA, yeah, at the end of, you know, 2019, yes.

Q. Did you tell the FDA that your company knew going back to at least July of 2017 and likely earlier, that you knew that NDMA was occurring in valsartan due to the quenching with sodium nitrite?

Did you tell that to the FDA?

A. I didn't have that knowledge, as I said. Although, you know, it looks like I was on the e-mail. But, as I said, I, you know --

Q. Did anybody tell that to the FDA from your company in 2018 or 2019 or 2020 or 2021?

MR. GALLAGHER: Objection. Outside the scope.

Page 176

To the extent you know, Dr. Li, you can answer.

A. Yeah, to the extent -- probably not, to the extent that I know.

BY MR. SLATER:

Q. Well, speaking for ZHP regarding the root cause investigation, as part of that interaction with the FDA on your root cause investigation, did you tell the FDA that you had knowledge going back to 2017 and likely earlier that quenching the valsartan with sodium nitrite was creating NDMA?

Did you tell the FDA that?

A. As I said --

MR. GALLAGHER: Hang on, Dr. Li. Sorry. Just pause for a minute after the question to give me a chance to object.

So objection, outside the scope.

The topic number 2 is the root cause investigation for nitrosamine impurities, including NDMA and NDEA in

Page 177

the ZHP API, as we've discussed that, and you have other topics about regulatory issues and discussions with FDA that's not within the topics for today. So outside the scope.

Dr. Li, to the extent you know personally, you can answer.

MR. SLATER: I'll ask the question again.

BY MR. SLATER:

Q. As part of ZHP's root cause investigation, did ZHP share with the FDA that ZHP knew going back to at least July 2017 and likely earlier that the quenching of the valsartan with sodium nitrite was the cause of the creation of NDMA?

MR. GALLAGHER: Objection. Outside the scope.

To the extent you know personally, you can answer, Dr. Li.

A. I think I already, you know, answered that question.

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Page 178

BY MR. SLATER:
Q. The answer is no, nobody told the FDA, right?
A. As far as I aware.
MR. SLATER: Cheryll, let's take this down and go, if we could -- see how quick you are -- to Exhibit 208, which is the FDA Draft Guidance from December 2008.
MS. CALDERON: It will take me a minute.
MR. SLATER: I thought you were going to pull it up and say you read my mind.
Q. Let me ask you this while Cheryll is looking for the document.
MR. SLATER: You can leave this e-mail up for a moment, Cheryll.
Q. Did ZHP ever share this July 27, 2017 e-mail with the FDA?
MR. GALLAGHER: Objection. Outside the scope.
Dr. Li, to the extent you know personally, you can answer.

Page 179

A. I don't know personally.
BY MR. SLATER:
Q. Did you tell the FDA, as part of your interactions with them when they were trying to learn the root cause of what had happened, that you had directed people in your department to cease work on a report that was being prepared regarding the creation of nitroso compounds due to sodium nitrite quenching because of the sensitivity of the impurity?
Did you tell that to the FDA?
MR. GALLAGHER: Objection. Outside the scope, mischaracterizes testimony and documents.
A. I didn't ask them to seize -- you know, to seize the work. The work has already been done, right.
BY MR. SLATER:
Q. Well, do you think the FDA would like to see that e-mail now? Do you think they'd be interested in it?
MR. GALLAGHER: Objection. Outside the scope, calls for

Page 180

speculation.
BY MR. SLATER:
Q. You've interacted with the FDA, you know the interest they have in this nitrosamine impurity issue. Do you think they'd like to see the e-mail now?
MR. GALLAGHER: Objection. Still calls for speculation.
A. I don't know.
BY MR. SLATER:
Q. We've put up on the screen Exhibit 208, the FDA "Guidance for Industry" regarding "Genotoxic and Carcinogenic Impurities in Drug Substances and Products," with the "Recommended Approaches."
And this is FDA guidance. You're familiar with this document, aren't you?
A. I read through it before.
MR. SLATER: And let's go to page 8, please, Cheryll, the top carryover paragraph, please. You got it. I just want the top -- the top of the page. Scroll up. Yes. Perfect.

Page 181

Q. Looking at the --
MR. SLATER: Can you scroll up more? Because it's confusing, actually. No, the other way. Yes. All right. Perfect.
Q. Looking at the carryover paragraph on page 8, they're talking about the threshold approach. And you've been talking about threshold during this deposition, correct?
A. We had some discussion, yeah, about the specification, yeah.
Q. And as of 2008, looking at the last sentence in that carryover paragraph on page 8, it says, "However, there are some compounds containing certain structural groups, (aflatoxin-like-, N-nitroso- and azoxy-structures) that have extremely high carcinogenic potency and are excluded from the threshold approach."
Do you see what I just read?
A. Mm-hmm.
Q. In terms of the knowledge of the health risks and what's acceptable, your

Page 182

company, ZHP, absolutely knew this after it came out in 2008, right?

MR. GALLAGHER: Objection. Outside the scope, and lacks foundation.

A. That was before my joining the company. I had no specific knowledge, but my guess, it should be -- somebody should have read through this document.

BY MR. SLATER:

Q. Certainly.

And in the context of Topic 36, which was ZHP's evaluation and knowledge of the health risks of nitrosamines, this is important information saying that N-nitroso structures "have extremely high carcinogenic potency and are excluded from the threshold approach."

That's an important piece of information, correct?

MR. GALLAGHER: Objection. Vague.

A. That's what it state in this document. Okay.

Page 183

But also, you know, I think in this document, or maybe in a more updated, you know, M7, it also said, you know, you know, these approach usually are very conservative.

BY MR. SLATER:

Q. Well, M7 says that "Some structural groups were identified to be of such high potency that intakes even below the threshold of toxicological concern would theoretically be associated with a potential for a significant carcinogenic risk. This group of high potency mutagenic carcinogens," referred to as the "cohort of concern," "comprises aflatoxin-like-, N-nitroso-, and azoxy compounds."

You know that's what M7 says, right?

A. Yes. But also it said potential, yeah.

Q. The point is this. The regulators around the world have determined that with the N-nitroso compounds, the risk of causing cancer to humans is too high to

Page 184

allow that to be in these drug substances, correct?

That's the decision that's been made around the world, correct?

MR. GALLAGHER: Objection. Outside the scope, calls for speculation, and calls for expert testimony.

A. As I said, you know, based upon some recently released material, training material by FDA, I think, you know, the potential risk -- our knowledge of the potential risk is still evolving, okay.

And also, as I said, some of the N-nitroso compounds, they are not genotoxic, okay, like impurity K.

But anything else, you know, I think it will up to, you know, a professional toxicologist, you know, to do further evaluation.

BY MR. SLATER:

Q. In terms of ZHP's evaluation and knowledge of the health risks of nitrosamines, you would certainly agree with

Page 185

me that with regard to NDMA and NDEA, the nitrosamines at issue in this litigation, they're considered to be high potency mutagenic carcinogens, correct?

A. They're considered to be -- well, those are the data based upon animal studies, okay. They are considered as potential or probable carcinogenic to humans, so this has not been fully confirmed.

Q. Based on the studies that have been performed, they're considered to be probable high potency mutagenic carcinogens. That's the considered wisdom at present, correct?

MR. GALLAGHER: Objection. Vague.

A. As I said, you know, the common consensus based upon FDA's release document or European, you know, regulators, yeah, NDMA or NDEA, they are potential or probable, you know, carcinogen to human.

BY MR. SLATER:

Q. The word is "probable." They're considered probable, correct?

Page 186

A. Probable, you know, which means it's not confirmed. It's not fully confirmed.
Q. You're a scientist. "Probable" means more likely than not, right?
A. Probably is probable, whatever that -- you know, yeah, we can look at the dictionary, yeah, probable, yeah.
But, again, probable, you know, you know, again, is not a sure thing. I mean, probable, you know, a lot of things could be probable but eventually didn't happen.
Q. You mentioned the word -- rephrase.
You used the word a moment ago "consensus." The consensus among those people who are responsible for this issue is NDMA and NDEA are probable human carcinogens, and they shouldn't be in drug substances for that reason, because it's considered to be too high a risk for humans, correct?
MR. GALLAGHER: Objection.
Vague --

Page 187

BY MR. SLATER:
Q. That's the consensus, right?
MR. GALLAGHER: Objection. Vague, calls for speculation, and expert testimony.
A. Your question is not accurate. You know, and I think I answered that question before, okay?
You know, based upon, you know, the current, you know, consensus, at least from FDA, okay, you know, based upon your process, I mean, obviously the best way would be to avoid. But we know, you know, for the -- you know, for the -- you know, for the valsartan, you know, you know, process chemistry, it looks like, you know, you just cannot avoid, you know, the formation.
So it's a certain level of NDMA would be allowed, okay. So, as I said, right now the consensus is 96 nanogram per day, okay. That's considered to be lifetime, you know, you know, allowable intake level.
BY MR. SLATER:
Q. The levels of NDMA in ZHP's valsartan far exceeded that level, correct?

Page 188

A. Based upon the current knowledge, yes.
Q. The levels of NDMA in ZHP's valsartan are considered to be unacceptable for human consumption, right?
MR. GALLAGHER: Objection. Vague.
A. That's retrospective. That's based upon today's knowledge, okay. This may change over time, you know, either be tightened or even maybe be loosened, okay, because the reason, again, you know, based upon FDA release the training document, you know, they endogenously formed NDMA, right?
As I said, you know, anybody like you and me, you know, just by, you know, changing the normal food, the NDMA then will be formed because of just simply by taking the food, it will be produced anywhere between 1,000 microgram to 2,000 -- you know, more than 2,000 microgram per day.
Q. What are you quoting for those numbers?

Page 189

A. Those are from the recent FDA trainings, you know, you know, document. I think, you know, my counsel can send these documents to you. I mean, these are, you know, publicly available information.
Q. Are you telling us that because certain nitrosamines can form at very low levels in nature, that it's acceptable that ZHP was selling valsartan --
(Over-speaking.)
A. No, no, no. Don't twist.
Q. Are you saying that or not?
A. No, I'm not saying that. I'm just saying the fact, okay? I'm not saying -- okay. What I'm telling you is several facts, okay, right?
First of all, you know, FDA's -- after the events, right, FDA's -- first of all, you know, at the time, you know, nobody knew, you know, you know, immediately what the -- you know, a limit or an interim limit should be, right?
And then so after some time, you know, the interim limit was established,

Page 190

okay? The interim limits was 96 nanogram per day, okay.

And then, you know, after some time FDA's position was that NDMA, also NDEA, should be absent, right?

And then more recently, you know, they loosened the standard, okay, they -- you know, the NDMA now, you know, being allowed, you know, to a maximum level 96 nanogram per day, right?

So -- but in the training, FDA's training material, you know, you know, they had those things, you know, they had, you know, those discussions.

So, yeah, so based upon that, you know, you know, you know, you know, the material -- okay, also based upon the principle of M7, right?

And that's a reasonable speculation that, you know, FDA or somebody -- you know, other regulator they may, you know, change the acceptable limits in the future, okay?

You know, because if you look

Page 191

at the -- you know, the M7, right, it says if data, you know, potential genotox impurity, if they -- you know, if they come, you know, if the source for another source, right, other than a medication is more than, you know, what you can take from a medical product, you know, then -- you know, then in general, you know, you know, their level, you know, may be -- you know, may be loosened, okay, based upon, you know, that fact.

Q. The levels of NDMA in ZHP's valsartan would never have been acceptable in 2014, 2015, 2016, 2017, or 2018?

MR. GALLAGHER: Objection. Vague, compound.

BY MR. SLATER:

Q. Do you agree with me those levels were so high, they never would have been acceptable in any of those years, correct?

MR. GALLAGHER: Objection. Vague, compound, calls for speculation, and expert testimony.

A. You know, retrospectively, you

Page 192

know, that would be the case. But don't forget, you know, we have the -- you know, we didn't have that specification. And all the, you know, all the specification that we tested, you know, and released upon, they have been submitted and also approved by regulatory agencies, including FDA.

BY MR. SLATER:

Q. Well, you're certainly not telling me that ZHP and yourself, who joined the company in 2014, could have thought that the levels of NDMA in your valsartan would have been acceptable back in 2014 or 2015 or 2016 or 2017 or 2018?

You're not telling me that ZHP would have thought these levels would have been acceptable, are you?

MR. GALLAGHER: Objection.

A. As I said --

MR. GALLAGHER: Wait, hang on. Objection. Vague, compound, calls for speculation, expert testimony, and asked and answered.

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Page 193

BY MR. SLATER:

Q. At that time, you didn't need to say it's retrospective. In 2015, for example, I'm looking at the levels on the documents submitted to the FDA. You had levels of over 100 parts per million in some batches.

You could never have thought that was acceptable to sell under any circumstances at that time, right?

MR. GALLAGHER: Objection. Vague, calls for expert testimony, argumentative, and lacks foundation.

A. Again, with a specific level, you know, this is outside of my expertise. As I said, this up to toxicologists, also regulators, you know, finally, you know, you know, their job to determine.

BY MR. SLATER:

Q. Validation batch number 1, batch number C5355-12-003 manufactured on December 28, 2011 was tested by your company at NDMA level of 76 parts per million.

That level, your company never

Page 194

would have thought was acceptable for sale at any point during the entire time valsartan was sold, correct?

MR. GALLAGHER: Objection. Outside the scope, vague, calls for speculation, and expert testimony.

THE WITNESS: I don't know, do I need to answer the question?

MR. GALLAGHER: Yes. To the extent you know, you should answer.

A. I mean, basically, as I said, you know, retrospectively, you know, you know, those levels are above the current, okay, established limit.

BY MR. SLATER:

Q. Those levels were so high that if your company had actually acknowledged to the outside world that NDMA was forming due to the sodium nitrite quenching, you know, and you can agree with me right now, your sale of valsartan would have been shut down immediately as soon as your company disclosed that, correct?

MR. GALLAGHER: Objection.

Page 195

Argumentative, calls for speculation, and expert testimony.

A. That's not the case, okay. As I told you, once we -- you know, after -- you know, after that particular event, after we have got, you know, those data, right, from the initial, like, 50 batches or so, we reported, you know, like up to two, three weeks roughly, we reported it to the FDA.

We asked them their guidance, okay, and we mentioned, I think, you know, at least in one of the communications whether we should do the recall. And they specifically told us to be hold on.

So this is not what you're saying, you know, you know, all right?

So, essentially, it need to be evaluated by, you know, experts.

MR. GALLAGHER: Adam, we've been going almost an hour and 20 minutes.

MR. SLATER: I just have a couple quick follow-up questions, and then we can take a break.

Page 196

MR. GALLAGHER: Okay.

BY MR. SLATER:

Q. The FDA never indicated that the NDMA levels in the valsartan sold by your company were acceptable. All they said is they had to figure out how much supply was out there due to the extent of the contamination of your pills, and they had to just make sure that there was enough medication out there for people's blood pressure to be controlled for a short period of time.

That's all the FDA let you do, right?

MR. GALLAGHER: Objection. Outside the scope, and lacks foundation.

A. I don't know, you know, because I'm not the person, you know, to be directly involved with the -- you know, with the recall.

So I don't -- you know, I don't know exactly, you know, what you, you know, just said to me, okay, but, you know,

Page 197

assuming that's true, so at least, you know, what that indicate, you know, there is no, you know, immediate, you know, you know -- I mean, it still be tolerable considered, you know, that particular medical need.

And again, you know, you know, the level, like you said, 70-some ppm, is not, you know -- you have saying, you know, you know, you know, consider, for example, like ranitidine, right?

If you look at ranitidine, okay, this is a compound or is a medication developed by, you know, GSK or its precursor, you know, company, like SmithKline, like about 40 years ago, okay?

And now we know that, you know, you know, the level, you know, you know, of this, you know, probably -- I think the actual level was like 47 micrograms or something.

So, yes, so that's, you know, higher than I think our, you know, you know, NDMA, you know, in those batches.

MR. SLATER: I think that we

Page 198

can take a break off of the ranitidine testimony and take a break, so we can go off the record.

THE VIDEOGRAPHER: The time right now is 11:01 a.m. We're now off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 11:16 a.m. We're back on the record.

BY MR. SLATER:

Q. We're looking at Exhibit 284, and this is an e-mail sent by some people at Novartis to ZHP on May 22, 2018.

Do you see that?

A. Yeah, it looks like, yeah. Mm-hmm.

Q. And the e-mail says, "Dear Huahai colleagues, During our analysis of residual solvents by GC (using a combined method) at Novartis we have found a number of solvents that we cannot identify for the following batches. The peak areas vary

Page 199

depending on the batch. These are the batches analyzed."

And they give the list of the batches, right?

A. It looks like, mm-hmm.

Q. And ultimately they also attach their gas chromatography method for ZHP to review and ask, "I would appreciate your support on this and feel free to call me if any further information is required."

So they were asking ZHP, what are these unknown peaks in these various batches of valsartan API, correct?

A. Yes, mm-hmm.

Q. And we know in retrospect, as you've said earlier, that gas chromatography-mass spectrometry, if focused at that time, would show NDMA, correct?

MR. GALLAGHER: Objection. Mischaracterizes testimony.

A. No, I didn't.

BY MR. SLATER:

Q. Well, let's go further then. Let's go now to Exhibit 288.

Page 200

And this is June 5, 2008 -- rephrase.

Looking now at Exhibit 288, this is a June 5, 2018 e-mail, again from Novartis to multiple people in your company, including yourself, correct?

A. Let me see whether -- am I on it? Let me --

Q. Second-to-last line of the CC list.

A. Oh, yes, mm-hmm. Yeah.

Q. You're there, and just above you is Peng Dong.

Do you see that?

A. Yes, mm-hmm. I saw him, yes.

Q. Two of the people who received that July 2017 e-mail we've gone through from Jinsheng Lin, correct?

A. Yes, mm-hmm.

Q. And at this point now Novartis advises you that "We have done some tests in Solvias labs for Novartis of three batches of Huahai material and have a tentative assessment."

Page 201

And they then point out that they're asking for your company to assess this and comment as soon as possible, right?

A. Yeah, looks like, mm-hmm.

MR. SLATER: And as we flip through, Cheryll, if could you go forward to the page that says 798, with regard to the first batch that was tested.

Q. Do you see there that there's identification of NDMA, and it says "tentative," correct?

A. Yes.

Q. And you're familiar with this document, right? So you know that for the next two batches, the same finding was made, right?

A. Mm-hmm.

Q. And the NDMA in the valsartan is what was discussed by Jinsheng Ling in the July 2017 e-mail, correct?

A. He was not specifically at the time talking about this particular peak. He just -- at that time he was making, you know,

Page 202

you know, a guess.
Q. He was -- well, he -- rephrase.
He said that NDMA occurs in valsartan when quenched with sodium nitrite, and this here in June of 2018 is Novartis bringing to your attention that they tentatively think they've identified a peak that shows NDMA in valsartan, correct?
A. Yes.
Q. At any point in the communications with Novartis, did you or anybody else from ZHP tell Novartis that your company knew at least as of July 2017 that NDMA was forming in the valsartan that was quenched with sodium nitrite?
Did you tell Novartis about that?
A. I don't remember what we responded. I mean, can you go down to the -- or go through the whole e-mail?
Q. Well, this is the e-mail. There's no response to it. That's the e-mail. You're seeing at the top of the first page --

Page 203

MR. SLATER: Cheryll, you can go back to the beginning.
Q. -- that is the e-mail.
A. That's the whole?
Q. So my question is this.
Did ZHP tell Novartis that ZHP knew at least as of July 2017 that there was NDMA in its valsartan? I just want to know if your company told that to Novartis.
A. I don't remember. I don't know. I mean, I -- you know, I was not involved, you know, in most of those, you know, you know, e-mail communication. I was -- some of those e-mail communication, just telling them about some technical issues, I think.
Q. Well -- rephrase.
Have you seen anything indicating that ZHP disclosed to Novartis when Novartis came with its concerns about these unknown peaks that your company already knew that there was NDMA in the valsartan?
A. I have no knowledge.
Q. You haven't seen anything that

Page 204

shows that that was disclosed, right?
A. Not as far as I know.
Q. Let's now go to Exhibit 289, which is the report from Solvias that was provided with the June 5, 2018, e-mail.
You've seen this report, correct?
A. Yes.
MR. SLATER: And let's go now to the second page of this document where the objective is listed.
Perfect.
Q. And the objective of this study was as follows. "Unknown compounds were detected in the analysis of residue solvents in Valsartan, a product of Novartis International Pharmaceuticals." I'll stop there.
And the reason it says that is because, as you know, Novartis had purchased this API from ZHP and then provided it to Solvias to test it, correct?
A. Yes.
Q. And then this says, "Solvias

Page 205

received the task from Novartis to analyse and identify the unknown compounds using Headspace GC/MS analysis."
And I want to stop there and ask you, "GC/MS analysis" is gas chromatography-mass spectrometry, correct?
A. Yes.
Q. That's a technology that's been available -- as of 2018, for how long had that been available?
A. It was quite long.
Q. And then it says, "This report summarizes the results of this analysis." Correct?
A. Mm-hmm.
Q. And by the way, when you say that GC-MS was available for quite a long time, it certainly was available as of 2011 when these processes were being developed by ZHP, correct?
A. It was available as an instrument, you know, to the market.
I just -- you know, you know, yesterday I just asked, you know, you know,

Page 206

Mr., you know, Chen, you know, Wenbin Chen, you know, also on one of the e-mails, I ask him when we receive the first one.

I think it was somewhere like in 2013, Huahai, or at least, you know, you know, that organization prior to my joining, you know, that technical, you know, supporting group, you know, was getting the first one somewhere in 2013, yes.

Q. When you're testifying right now, are you testifying that you know that ZHP got its first GC-MS machine in 2013?

A. Yes.

Q. Are you sure they didn't have one earlier?

A. Well, at least not in my organization, on my prior, you know, organization that I inherited.

Yeah, they may have -- I don't know. I mean, like, you know, in the headquarters, you know, organizations, you know, like in Xunqiao, right, yeah, that was the first GC-MS that was there.

Q. One of the things that a

Page 207

company like ZHP should do is make sure that it obtains the type of technology that's available for it to manufacture quality substances, correct?

MR. GALLAGHER: Objection. Vague, and outside the scope.

A. You know, the residual solvent method typically uses GC-FID technology, okay? So for those, you know -- so typically people will not do the GC-MS, you know, to develop a residual solvent method.

BY MR. SLATER:

Q. It's been known since the 1970s and going back that GC-MS is the best way to identify nitrosamines, correct?

MR. GALLAGHER: Objection. Vague, lacks foundation, calls for speculation and expert testimony, and outside the scope.

MR. SLATER: It's outside the scope of the chromatogram and mass spectrometry with --

(Over-speaking.)

MR. GALLAGHER: I would

Page 208

withdraw the outside the scope objection.

But it's vague, lacks foundation, and calls for speculation and expert testimony.

BY MR. SLATER:

Q. You know that, right, that it's been known for many years, going back at least to the 1970s, that GC-MS is the best method to identify nitrosamines, correct?

MR. GALLAGHER: Same objections.

A. I only know retrospectively people have done, you know, previously, but not, you know, with valsartan or any other sartans.

And, you know, when you mentioned 1970s, I don't remember, you know, you know, the specific time frame.

But again, GC-MS has been mostly, you know, more like a research tool for QC residual solvent method. GC-FID method remains to be, even as of today, you know, the choice of, you know, of the method

Page 209

for controlling residual solvents.

MR. SLATER: Well, let's now go to page -- the Bates number is 13 in the bottom right. Keep going. Let's get the whole bottom half of the page in. Perfect. Thank you, Cheryll.

BY MR. SLATER:

Q. Looking now at Figure 2 in the Solvias report, it's a chromatogram of valsartan, and it has the batch number 18-038M01, provided by Novartis to Solvias.

Do you see that?

A. Mm-hmm.

Q. Can you tell what type of chromatogram that is?

A. Yeah, it looks like a chromatogram from GC-MS analysis.

Q. And if you look at it, it says that Table 4 -- rephrase.

First of all, looking at the chromatogram itself -- actually, we'll come back to that. Looking at -- rephrase.

Below the Figure 2, the chromatogram, it says in part, "Table 4

Page 210

displays the corresponding retention times and calculated relative retention times."
Do you see that?
A. Mm-hmm. Okay.
MR. SLATER: And if we scroll to the next page, and then we'll scroll back in a moment, but if we scroll to the next page -- perfect.
Q. You see at number 18 toluene with a retention time of 10.46.
Do you see that?
A. Mm-hmm.
Q. And then right below it, number 19, it says "not applicable, 12.25."
Do you see that?
A. Mm-hmm.
Q. And the "not applicable" there means it hasn't been identified, right?
A. Probably.
Q. And then if you scroll further down into the next table, 5, it says "Tentative identification of unknown peaks detected in Valsartan."
MR. SLATER: Cheryll, if you

Page 211

scroll further, please.
Q. 18 and 19 matching up again, at 18 we have toluene, correct?
A. Mm-hmm.
Q. And 19, NDMA, and they call it "tentative," right?
A. Right.
Q. So based on this, if we go back now to the chromatogram at Figure 2, the toluene is that peak on the right, the taller peak third from the right. And I know that the writing is incredibly small. We can probably blow it up quite a bit.
MR. SLATER: So let's do that.
A. Sure.
Q. I don't know if we can blow it up enough, but I can tell you --
A. Okay.
Q. -- that says toluene, 10.46.
A. Okay. All right. Okay. This one. Okay.
MR. SLATER: Good job, Cheryll.
Q. And then the NDMA peak that they identified at 12.25 --

Page 212

MR. SLATER: If you scroll down a little further down, Cheryll. Perfect. And scroll to the right so we can see the peak to the right.
Q. That next peak to the right of the toluene is 12.25.
Do you see that?
A. Yes, mm-hmm. Okay.
Q. And to -- rephrase.
And using your terminology, in retrospect and as proven -- well, rephrase.
As proven here and as you subsequently confirmed, that's the NDMA peak, correct?
A. I don't know, you know -- wait a second. I think on the table, you know, you know, it was their method. This is not NDMA. I think, you know, if I remember correctly just moments ago, the other way should be like, what, 15 something, or what? Can you go down the list?
Q. Sure. And you can tell me which one is the NDMA peak. Why don't we do that.

Page 213

A. Well, you know, I'm not very familiar with Novartis', you know -- you know, all of those details, okay. Yeah, going down the other -- yeah.
MR. SLATER: Go to the next table, Cheryll.
A. Yeah, yeah, yeah, yeah, yeah. Because I don't think -- yeah, it shows the retention time like 15 something. 19.
Yeah, 15 -- yeah, see that, yeah, 15 point -- almost 16 minutes. So it should not be that one immediately after, you know, the toluene with their method.
Q. Well, in fact, if you look at the retention times for the two different tables, they're actually different, and the one that matches up to the chromatogram is the 10.46 and the 12.25.
Do you know why those numbers are different?
A. I don't know. I mean, it's their method.
THE WITNESS: Can we go up, yeah, and take a look at toluene in

Page 214

the first table? Yeah. I mean, this one -- yeah.
A. See where the toluene -- yeah, on the first table -- what's the retention time?
Oh, hold on. I'm sorry. Okay. Okay. So -- okay. So, yeah, somehow, you know, the retention time, they're quite different. On this table toluene is like 10.46, yeah.
MR. SLATER: Let me see if we can -- go to the chromatogram, please, Cheryll. Just let's go to the picture.
Q. Maybe we can find a common ground. What we do know is this. The toluene elutes, and then the NDMA elutes to the right of it, correct?
A. No. Actually, if you're talking about, you know, ZHP's method, okay, what I can tell you the profile.
Okay. Yeah. So we have the toluene and then we have the next, like, somewhat, you know, more obvious peak, like

Page 215

the one, you know, you just trying to point out to me like 12 point something, right? But I'm not saying our method, you know, they have this retention time, okay. I'm just talking about, you know, you know, the elution profile, okay?
So after the first somewhat more obvious peak, after the toluene, based upon our, you know, analysis, it's not NDMA, okay? That, you know, that peak was n-butyl acetate, okay? And so based upon our analysis retrospectively, the NDMA eluting at the shoulder peak of the n-butyl acetate.
Q. Okay. So -- rephrase.
So the NDMA is to the right of the toluene, correct?
A. It's right to the toluene, and also it's right to the first -- you know, yeah, right to the n-butyl acetate.
Q. And on this test Solvias was able to tentatively identify the NDMA peak, correct?
A. Based upon, yeah, their report, yes.

Page 216

Q. And let me -- explain -- tell me if I understand this correctly. If you do an appropriate risk assessment and know that NDMA potentially formed, and you used GC-MS and looked for NDMA, you can find it, right?
MR. GALLAGHER: Objection. Vague and compound, and calls for speculation.
A. I mean, retrospectively, if you want to specifically look for it using GC-MS or, you know, GC-MS/MS, yeah, you might be able to find it, yes.
BY MR. SLATER:
Q. And that's ultimately what happened, right? When ZHP was looking for it after Novartis came to you, you identified it, right?
A. Yes.
Q. And in fact, as we've talked about earlier in the deposition, we've now seen an e-mail showing that it was discussed within your company almost a year earlier, that your company already knew that NDMA was in the valsartan, correct?

Page 217

A. It's not, you know, ZHP knew. I mean, it was Mr. Lin, you know, he made that speculation.
Q. He shared that information with you, Peng Dong, Linda Lin, Jucai Ge, people who had important positions in ZHP, right?
MR. GALLAGHER: Objection. Vague.
A. People who are employed by ZHP at the time, yes.
BY MR. SLATER:
Q. In important positions, in high-level positions, correct?
MR. GALLAGHER: Objection. Vague.
A. For some of them, I'm not sure. You know, it could be defined as high-level. For myself, yes, I'm at a high-level position, but not necessarily for every single one of them.
BY MR. SLATER:
Q. Peng Dong had a -- what about Peng Dong? What position was he in?
A. He was -- probably at the time

Page 218

was a technical manager, so I would say this is a middle-level.
Q. How about Jucai Ge?
A. She was the QA. You know, she's a QA person, yeah. She's responsible, you know, for the QA department.
Q. The QA is the quality assurance department, right?
A. Right.
Q. What does the quality assurance department do?
A. They want to ensure, you know, product being manufactured according to, you know, predefined or particularly, you know, file the registrations for the regulatory authorities.
Q. And Linda Lin was in the regulatory affairs department, correct?
A. Yes.
Q. She had a significant position, right?
A. She's the head of the regulatory affairs.
Q. And all of those people were

Page 219

put on notice at least as of July 2017 that there was NDMA in the valsartan, right?
A. I mean, based upon that e-mail, I mean, you know, Mr. Lin made that e-mail. But again, you know, it looks like -- you know, it's just people maybe didn't go through or people maybe just saw that he's making, you know, exaggerations or...
Q. But in reality he was right, and that's been proven, correct?
MR. GALLAGHER: Objection. Asked and answered, and mischaracterizes the testimony.
A. As I --
I mean, do I need to answer?
MR. GALLAGHER: You can answer.
THE WITNESS: Okay.
I mean, as I, you know, answered earlier, I mean, basically, you know -- you know, at that time, you know, you know, as I said, he was making his guess.
But also, you know, the topic of the e-mail was talking about

Page 220

irbesartan, not -- you know, that particular irbesartan, you know, N-nitroso compound of the irbesartan, so it's not, you know, NDMA.
BY MR. SLATER:
Q. Well, you knew in April 2018 that you didn't want that report that your department was working on to be completed or shown to anybody, and that's why you said --
A. No. No, it's --
Q. -- not to go further with that report, right?
A. Well, see, I mean, you know, the -- you know, as I said, the work has already been -- you know, been done.
You know, the reason, as I have explained, you know, I don't want to create a confusion, you know what I'm saying? And, you know, you know, was mixed up with, you know, those things.
You know, because, you know, the topic of that document, you know, was about, you know, an impurity. That impurity was not even, you know, you know, you know,

Page 221

in a real impurity present in a commercial product.
I mean, it was during, you know, the -- you know, the further -- or the trial, you know, in order to further, or trying to, you know, improve the quenching process of irbesartan.
Q. And Mr. Lin, who was doing a very good job at the time, said, if this is a nitroso compound, we have a real problem here, similar to the problem we have with valsartan.
He was doing a good job, and turned out in the end to have been the correct person, right?
MR. GALLAGHER: Objection. Compound, mischaracterizes testimony, asked and answered.
A. Again, you know, as I said, at least at that time or, you know, those guess or projection, you know, as I indicated to you, not all he said, you know, was correct, okay?
Some he's making -- you know,

Page 222

he's, you know, guess, and he's also, you know, particularly with regard to, you know, the potential toxicity of the irbesartans, that particular N-nitroso derivative of irbesartan.

You know, I don't think, you know, it was appropriate for him to make that judgment. You know, he is not a toxicologist.

MR. SLATER: Cheryl, let's go to Exhibit 234, if we could, please, which is the other document that was provided in that Exhibit 288 to Novartis by ZHP.

That is not the document I was expecting. I gave you the Bates number. It should be the "Study Report of Unknown Peak in Residual Solvent of Valsartan."

THE WITNESS: Okay.

MR. SLATER: I'm talking to Cheryl, though, but it's going to come to you in a moment.

THE WITNESS: Okay.

Page 223

MR. SLATER: One second.

Cheryl, what exhibit is this?

MS. CALDERON: I have to check. Give me one second.

MR. SLATER: I had 234 on it. I want to make sure we have it for the record.

MS. CALDERON: I'm not sure. I have to look. It's not --

MR. SLATER: I don't want to waste any more time with this, so let's just mark it again. What number are we up to?

THE STENOGRAPHER: 305.

(Whereupon, Exhibit Number ZHP-305 was marked for identification.)

BY MR. SLATER:

Q. Do you see what we've put up as Exhibit 305, "Study Report of Unknown Peak in Residual Solvent of Valsartan"?

A. Mm-hmm.

Q. You're familiar with this, correct?

Page 224

A. I went through this report, yes.

Q. Okay. And if we turn to the next page, it's dated May 31, 2018, correct?

Do you see that?

A. Yes.

Q. If we turn to the next page, it was actually signed off by several people, including --

MR. SLATER: If you could turn to the next page, Cheryl. Thanks.

Q. You see it was signed off by multiple people, including Peng Dong, correct?

A. Mm-hmm.

MR. SLATER: And now if we go to the next page, please. Let's go past the "Contents." I'm sorry. Let's go to the "Background" section, next page. So we're now on page 2 of 23.

Q. So there's a "Background" section of this report that talks about the fact that there were many unknown peaks

Page 225

identified with the residual solvent for valsartan with the Huahai method, correct?

A. Yes, mm-hmm.

Q. And just below that "Background" section there's Figure 1, which is titled as a "Typical chromatogram of Huahai method."

Do you see that?

A. Mm-hmm.

Q. What does that mean, "typical chromatogram"?

A. "Typical" usually means representative, which means, you know, it can be an example to illustrate.

Q. And it says "FID." So is this a gas chromatography-FID test?

A. Yes.

Q. And you can see a little better on this -- rephrase.

And you can see the peaks are labeled, and the peak that's labeled farthest to the right with a label is toluene.

Do you see that?

A. Yeah, mm-hmm.

Page 226

Q. And then there's a series of unidentified smaller peaks to the right of that?
A. Yes.
Q. And without figuring out which one it is or exactly where it is, we know in hindsight that the NDMA can be identified there if one looks for it with gas chromatography-mass spectrometry, correct?
A. No, that's not correct.
Q. If you were to be asked to go and use GC-MS to look for NDMA, you don't think you could identify it on this sample?
A. GC-MS and GC-FID, they are two different, quite different methods.
Q. No, let me ask the question differently, because that's not what I -- I get why you're saying that, though.
If one decided to test by GC-MS instead of GC-FID, this batch, and actually looked for NDMA, it would be able to be identified with the GC-MS, correct?
A. If you -- what we found out, okay, if you just use, you know -- you know,

Page 227

basically if you use the conditions, right, including the sample concentrations as in this GC-FID method, if you then turn that into a GC-MS method based upon our retrospective, you know, analysis, you will not be able to see NDMA, okay?
And then I think that during this investigation, the concentration of the sample, you know, was increased by 20 times. And even that, with the GC-MS chromatogram, you know, you can see, you know, I think in some of the figures, you know, I think in some of the figures, you know, in this report the NDMA peak was still not very obvious. It was buried among other, you know, unknown peaks.
Q. The other night Qiangming Li testified that the NDMA peak eluted on the GC-FID between 14.2 and 14.5.
Does that sound correct to you?
A. I don't know. I mean, because -- from --
MR. GALLAGHER: Objection.
THE WITNESS: Sorry.

Page 228

MR. GALLAGHER: Go ahead.
A. You know, you know, I cannot confirm, you know, the specific time range, okay. But I can tell you, you know, just look at this, you know, you know, Figure 1, right.
You know, basically after the toluene peak, you have like three, right, roughly three peaks, right? You see that? Three little peaks?
Q. Yes.
A. Right? Okay. As I, you know, communicate, you know, to you earlier, the first little peak appears to be -- okay, there are two folds, okay.
In the blank injection, there was also a blank peak, okay, eluting at that region, okay.
With the real sample, at least for some batches, okay, what we found is, you know, this peak was n-butyl acetate, okay, and then NDMA, you know, you know, it would elute at the shoulder, you know, you know, you know, of this peak. If you, you know,

Page 229

making a reference then of NDMA with high enough concentration, you know, it will, you know, show a peak at that region.
But with the regular batch, basically, you know, the NDMA is just -- you know, sometimes, you know, it just co-elute, complete co-elute, sometimes may be a very tiny, you know, shoulder peak there.
Q. Solvias found it, right?
A. They were using a quite different, okay, method, okay. If you notice, you know, one of the, you know, major differences, they were using NMP as the sample. You know, this particular method, ZHP's method utilizing DMSO, okay.
So when you use different sample diluents, you will have different background peaks, okay?
So at that particular region, when they turned that -- their NMP method into the corresponding GC-MS method, and also because, you know, the -- because NMP, you know, is a higher-volume point as compared to DMSO, right? So we did a comparison of the

Page 230

two methods.
Their, you know, like incubation temperature, I think it was like at least 15 degrees Celsius higher, you know, you know, than the ZHP's method.
So the bottom line is, you know, their GC-MS method appears to be more sensitive than ZHP's, you know, GC-MS method.
Q. The point is, the technology and the methodology was clearly available to identify the NDMA, correct?
A. Well, but first of all -- yes, the answer is yes, but, see, the first -- you know, you need to know what to look for, right? Yeah.
Q. When you say "you need to know what to look for," you're talking about a risk assessment, right?
A. Right.
Q. And that's a very important part of testing, is that the risk assessment done as the threshold needs to be thorough, right?
MR. GALLAGHER: Objection.

Page 231

Vague.
BY MR. SLATER:
Q. I'll ask it differently.
The risk assessment is the step that's taken before you do the testing so that you have thought through what you should be looking for, correct?
A. The risk assessment is actually in the very beginning of the development of this particular valsartan process. So as a QC, you know, you know, as a daily QC operation, you don't do the risk, you know, you know, you know, assessment, you know, at that period.
Q. Well, if you get back -- rephrase.
If you have a customer like Novartis that comes to you and says there's unknown peaks, part of the way you then try to study and figure out what those peaks are is to do a risk assessment to figure out what might they be so you know what you should look for, correct?
A. Well, you know, you know, in

Page 232

this particular case with Novartis, you know, they -- you know, in the very beginning, you know, they were raising some specific, you know, unknown impurities with a defined retention time. Okay.
So throughout this process we have been working with Novartis, you know, to try to identify those little unknown peaks.
Q. When you were working with Novartis to identify the peaks, did anybody from ZHP tell Novartis that you knew that NDMA is in the valsartan so that they would know to look for the NDMA?
A. I don't think people involved, you know, in the communications, you know, directly with Novartis, you know, had that knowledge before the events.
Q. Well, we know Peng Dong signed off on this unknown peak report, and he was on the e-mail in July of 2017, right?
A. He was. But I don't know how much, you know, you know, you know, he really went through, or -- basically, you know, I didn't know what happened, you know, after

Page 233

Mr. Lin, you know, sent out his e-mail.
I mean, it looks like nobody responded to anything, so I don't know. People may just, as I said, for whatever the reason, there's no, you know, resonance, I will say.
Q. With regard to the risk assessment that needed to be done -- well, rephrase.
With regard to the risk assessment, you pointed out it's done in the very beginning when the process is developed. But that's also an ongoing process, risk assessment, during the lifecycle of the drug substance, correct?
A. There is an ongoing, but usually with a particular, you know, you know, reason, yeah.
Q. So, for example, where a customer says, there's unknown peaks, we want to know what these are, we want to know what these potential impurities are, that's a reason to perform a risk assessment in conjunction with the testing, right? That's

Page 234

good science, right?
A. Well, based upon, you know, you know, you know, retrospective, you know, you know, communications, right. And the ZHP teams, you know, looks like, you know, focus on what the customer, you know, communicated, you know, to the team.
Q. Well, what I'm asking is this. It's good science under these circumstances, where a customer reports unknown peaks and is concerned about impurities, to do a risk assessment, evaluate the chemical reactions that can occur, and have some idea of what you're looking for, right?
That's good science, isn't it?
A. Well, usually what happen, okay, when people, you know, you know -- you know, first of all, okay, for a -- like a residual solvent method, right, like a GC-FID method, there is no -- like a threshold for any unknown peak, you know, to be identified, even as of today. Okay.
So when people talking about these small unknown peaks, you know, that's

Page 235

how people, you know, treated it, you know, initially as a technical issues, and so people focus on trying to resolve, you know, those identities, you know, to the customer.
Because the customer wanted to have very specific answers, right, and so -- you know, so from my, you know, understanding, you know, they -- at least at the time they were not requesting, you know, for anything other than they were, you know, you know, requested.
So, yeah, so that's how, you know, the focus of the ZHP team basically, you know, just tried to, you know, meet, you know, the needs of the customer to get the answer to them as soon as -- you know, as they can.
Q. The quickest way to get the answer to Novartis would have been to tell them that there was NDMA in the valsartan, right?
A. As I said, the team, you know, you know, the people involved, you know, directly with the communication, you know,

Page 236

they -- you know, as I said, like you said, you know, like Mr. -- although Mr. Peng Dong, you know, he was signing off and he was on the e-mail, but, you know, whatever, you know, for that reason, you know, basically, as I said, you know, Mr. Lin's e-mail just, you know, for whatever reason didn't generate, you know, any resonance.
Q. Well, it generated a report that in April of 2018 you directed your team not to complete and not to issue because there was a sensitive impurity discussed.
A. This impurity --
MR. GALLAGHER: Objection.
BY MR. SLATER:
Q. Isn't that why it didn't resonate?
MR. GALLAGHER: Objection. Outside the scope, mischaracterizes testimony, and mischaracterizes the document.
A. As I indicated, you know, that impurity is completely different from NDMA. I mean, that's the N-nitroso derivative of

Page 237

irbesartan, so it's completely different.
BY MR. SLATER:
Q. Before we go back into this report, I just want to make sure we're on the same page.
The assessment of the potential explanation for the impurities involves a chemical analysis, right? You have to do that analysis as part of the testing process, right?
A. No. Well, typically you do a mechanistic analysis, you know, based upon that mechanistic analysis or based upon the knowledge when this particular process was developed, right.
And if the analysis, you know, indicate there's some level of risk, then you will follow up to do a -- what is called a confirmatory testing.
But if the risk assessment, you know, at that time, or if the knowledge, you know, because of the knowledge gap, you know, it didn't turn up as a risk, you -- you know, you would not necessarily, you know, to do,

Page 238

you know, you know, an analysis.
Q. Was CEMAT doing this testing that's represented in this unknown peak study?
A. This particular work, you know, in this report, okay, it was done, you know, you know, you know, by the QC as well as, you know, with, you know, CEMAT, yes. So it's a combination, yes.
Q. Were you involved?
A. I was not directly involved.
Q. Did you have visibility to it? Were you aware of what was being done?
A. Well, only at the time, you know, they couldn't figure out, you know, some identities, you know, of a particular unknown peak, then they will come to me, you know, asking for possible solutions.
Yeah, I did help him, you know, provided some strategies, you know, to help him -- to help them, you know, getting, you know, the elucidation of some, you know, unknown peaks.
Q. And what strategies did you

Page 239

help with?
A. One of the strategy that I told him to use is to use butyrated DMSO.
The reason for that is, you know, quite a few of those interfering or background peaks, they were minor degradation products of DMSO, okay, with this particular method because DMSO, you know, you know, retrospectively that we found that, you know, it -- or during the process of this investigation we found out it will decompose to give, you know, a number of, you know, minor degradants.
I think some of those are, you know, you know, mentioned in the reports, like dimethyl, you know, you know, sulfide or dimethyl disulfide.
So the reason that I suggest them to use butyrated one is that, you know, you know, based upon the GC-MS analysis, you can -- if you see any peak, right, with what we call the mass shift, okay, and then we can basically, you know, understand, you know, the origin of that unknown peak, whether it's

Page 240

originated from DMSO or it's originated from some other reasons.
MR. SLATER: Cheryll, let's go in this report to page 19 of 23, please. Or not.
MS. CALDERON: You know what?
MR. SLATER: Frozen?
MS. CALDERON: I am frozen. Can you hear me?
MR. SLATER: Yes.
MS. CALDERON: Okay. Can you repeat what you said? Because I froze.
MR. SLATER: Sure. If you could turn to page 19 of 23, please.
MS. CALDERON: Okay. Sorry.
MR. SLATER: No problem. The thing doesn't want to move.
THE WITNESS: It's getting late.
MR. SLATER: It's worn out.
MS. CALDERON: Let me restart.
MR. SLATER: I think you were there. Oh, okay.

Page 241

MS. CALDERON: How's that?
MR. SLATER: I'll let you know when it comes up.
Perfect. Scroll up a little tiny bit more, get the whole risk assessment in there. Perfect.
BY MR. SLATER:
Q. This study report of unknown peaks from May of 2018 contains a Risk Assessment here on page 19.
Do you see that?
A. Mm-hmm.
Q. And the Risk Assessment says, "It is shown from above, each unknown peak has either been identified or the source of which identified, and the results are far lower than the specification by quantitative analysis." I want to stop there.
The reference to "specification" has to do with already identified solvents or other substances that you already know may be there, correct?
A. In this particular case, yes. It looks like utilizing 10 percent of the

Page 242

toluene ICH, you know, standard.
Q. And it says, "Control of these unknown peaks by comparing to the peak area of 10 percent toluene (ICH limit 89 parts per million) presents no risk." And then it says, "Please refer to the following table for details."
I want to stop there. When it refers to 89 parts per million presenting no risk, is that a judgment that was made that as long as something that's not identified is less than 89 parts per million, you don't have to worry about it?
A. Well, this 89 percent numbers or criteria, based upon, you know, what I was told, you know, it came from one of Novartis' document.
So basically during -- in our conversation, you know, at least at one time, the Novartis practice was that, you know, at that time, you know, you do not necessarily need to investigate any unknown peaks, okay, with peak area lower than toluene, you know, standard of -- you know, or toluene, you

Page 243

know, reference solution has 89, you know, ppm concentrations.
Q. Coming back to my question, it appears to me the risk assessment was as long as an unknown peak is less than 89 parts per million, there's no risk; you don't have to be concerned about it even if you can't identify what it is.
Do I understand that correctly?
A. No. That's not what it says. I mean, basically, you know, it looks like whoever made that risk assessment, you know, people utilized, you know, what Novartis at least, you know, you know, had done, you know, at one point.
Because even as of today, you know, as to what a threshold, you know, you need to identify for unknown peaks with GC-FID method. Is still -- there's no fixed answer to that.
Q. Well, the answer is that the NDMA -- well, rephrase. We'll come back to it.
MR. SLATER: Let's go now to

Page 244

the conclusion on page 23 of 23. Can you scroll up just a little bit just so we capture the bottom of the conclusion, please? Perfect.
Q. The conclusion of the report repeats the risk assessment, saying that "The unknown peaks can be controlled by comparing to the peak area of 10 percent toluene, ICH limit (89 parts per million). The product quality is less likely to be impacted."
Same conclusion as the risk assessment, right?
A. Mm-hmm, yes.
Q. Now, in retrospect, there was NDMA there, and that was affecting the quality of the product, right?
A. Yes. But here, you know, the subject of this investigation, you know, would focus on that nine, you know, unknown peaks. So that conclusion was made based upon assessment of those nine unknown peaks. So NDMA was not among one of them.
Q. Okay. Well, when you say NDMA was not among them, NDMA was not being looked

Page 245

for because nobody actually said we need to look for NDMA, right?
A. Well, whoever -- you know, you know, people doing this particular, you know, or people -- I mean, particularly the main -- you know, the main author, right, you know, of this investigation, he had no knowledge.
Q. And he didn't -- he didn't do or didn't have available to him a risk assessment advising of the potential development of NDMA, right? That was not provided, correct?
A. I don't know whether, you know, somebody provide it or not. But based upon, you know, what's presented here, you know, it looks like the risk assessment was solely based upon, you know, that nine unknown peaks.
Q. And the person who authored this report certainly didn't document knowing what was known by others in the company, that there was NDMA in the drug substance, correct?
A. As I said, you know, the main

Page 246

author, he had no knowledge.
MR. SLATER: Why don't we go off the record for a second.
THE VIDEOGRAPHER: The time right now is 12:13 p.m. We're now off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time right now is 12:26 p.m. We're back on the record.
BY MR. SLATER:
Q. So we have on screen Exhibit 213, which is an FDA Warning Letter dated November 29, 2018.
Do you see that?
A. Mm-hmm.
Q. And you understand this warning letter followed from the FDA inspection from July 23 to August 3 at ZHP's facilities, correct?
MR. GALLAGHER: Objection. Outside the scope.
You can answer to the extent

Page 247

you know personally.
A. Well, that I know, it's issued after the inspection.
Q. Right. And you can see in the first paragraph the dates of the inspection were July 23 to August 3, 2018.
Do you see that?
A. Yeah, mm-hmm.
Q. So if we scroll down a little further down on this page, deviation number 1 is titled, "Failure of your quality unit to ensure that quality-related complaints are investigated and resolved." Right?
A. I saw the title.
MR. SLATER: Let's go down to the next page and look at part of what was discussed somewhat relevant to what we just talked about.
You can scroll down further, Cheryll, because I want to -- that's good right there. Thank you.
Q. So you see a paragraph that starts with the word "Our investigators"?
A. Mm-hmm.

Page 248

Q. The FDA advised your company, "Our investigators also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms."
I want to stop there. That's what we were just talking about, is ZHP's study report on unknown peaks in May of 2018, correct?
A. I'm sorry, say that again?
Q. We were just discussing the study report of unknown peaks in residual solvent of valsartan a few moments ago, correct?
A. Right, mm-hmm.
Q. And here the FDA's pointing out that they thought that the investigation of unknown peaks observed in chromatograms was inadequate.
That's what the FDA found, correct?
A. That's what they statement. I think we had a -- you know, an explanation and a response.
Q. This points out, "For example,

Page 249

valsartan intermediates," and it gives some numbers of those batches, "failed testing for an unknown impurity (specification less than or equal to 0.5 percent) with results of 0.56 percent for both batches. Your action plan indicated that the impurity would be identified as part of the investigation; however, you failed to do this."
A. No, we did that, actually. We did afterward. I mean, at the time of this warning letter, you know, the investigation, I think, was still ongoing, okay.
So actually as part of the -- you know, of the CAPA or the commitment, you know, we actually, you know, did an investigation, but we didn't resolve, you know, the whole structure, okay.
And we, you know, you know, we told the, you know, the investigator, you know, this is a process impurity, you know, structurally related to that of valsartan intermediate. But we didn't know its exact structure, right?
So, yeah, so the investigation

Page 250

was ongoing, and eventually, you know, we resolved, you know, you know, that structure, okay.

Q. You said you resolved that structure.

A. Right.

Q. You mean you find NDMA?

A. Yes, finally with NMR we were able to identify those structures, yes, and which is confirmed it is a process-related, you know, impurity of that intermediate.

Q. But by this time it was already identified as NDMA, right?

A. You mean by the time of -- yeah, of this warning letter, yeah. NDMA, yes, that already was identified. But this is -- you know, FDA was talking about, you know, this is, you know, a completely different impurity. Yeah.

Q. What do you mean, the FDA's saying it's a completely different impurity?

A. Well, you know, here they specifically pointing out to -- you know, to that, you know, particular impurity, you

Page 251

know, given a value of 0.56 percent, right? Yeah. So, yeah, so that's not an NDMA or any other nitroso, you know, compound.

Q. So coming back to the FDA's comments, they're indicating that -- rephrase.

Coming back to the FDA's warning letter, the FDA stated your action plan, that would be ZHP's action plan, given on a prior date, correct?

A. Yeah, our plan is, you know, we will continue, you know, to do, you know, the structure elucidation, okay.

Basically, you know, as part of, like, this OOS investigation, okay, although, you know, we tried to identify unknown peaks as soon, you know, or as quickly as possible, but sometimes, you know, an unknown peak, you know, structure takes time, right.

So during that kind of, you know, you know, situation, what you can do is, you know, basically once we know, you know, you know, the basic information of this

Page 252

particular impurity, and also I think we did the assessment at the time, this impurity is just not -- you know, actually was not being carried over into the downstream product, right?

So, therefore, you know, the risk was, you know, was very limited or negligible. So that's how, you know, QA decided, you know, to, you know, basically to close the main investigation, but with a follow-up, you know, cover. Okay. That's a very typical, you know, way, you know, you know, in the industry, you know, to do those, like, impurity related, you know, investigation.

Q. Well, the FDA didn't seem happy with status of the investigation.

A. Well, that's -- I think that's their, you know, misunderstanding, you know, from my perspective.

So I think, as I said, during the final meetings or the last meeting, you know, being on-site at FDA, and also in our follow-up, you know, responses, you know, we

Page 253

stated very clearly, you know, you know, to the FDA, you know, this follow-up action has been completed. Yeah.

Q. The FDA continues to state, "Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your zinc chloride process, with DMF in 2012," and then it gives the three validation batch numbers, "show at least one unidentified peak eluting after the toluene peak in the area where the presence of NDMA was suspected to elute."

A. Again, you know, this peak, as I indicated to you, based upon our retrospective analysis, that first, you know, you know, visible, you know, small peaks based upon our investigation, it was n-butyl acetate.

Q. And I think you explained the NDMA was right next to that.

A. It's on the shoulder. As I said, after if we inject it with a, you know, a more concentrated sample, like a pure sample, right, and -- you know, then we would

Page 254

find out.
But in the chromatogram of a real sample, right, you know, like we analyze using the GC-FID method.
To analyze a real sample, the NDMA peak was basically, you know, submerged with, overwhelmed by this, you know, proceeding peak which is the n-butyl acetate.
Q. As a matter of good manufacturing practices, it's not acceptable to do a test, not identify the peak, and just say, well, it's pretty small, so we don't really have to worry about identifying it.
That's not acceptable, right?
MR. GALLAGHER: Objection. Vague, and calls for speculation.
A. We follow ICH guidance, okay, in terms of, you know, what needs to be identified, what -- you know, you know, you do not necessarily need to identify it.
BY MR. SLATER:
Q. It's not acceptable where you're trying to identify what an unknown peak is to run your standard test, not

Page 255

identify it, and just assume it's fine, because you know that even something with a very, very small peak, something that's barely perceptible, if it's a mutagenic/genotoxic impurity, that can be dangerous and can't be in the product, right?
MR. GALLAGHER: Objection. Vague, lacks foundation, and compound.
A. You know, for those very low-level potential genotoxic impurity, you would need to develop a specific method, okay, to -- you know, to detect them, to control them, okay.
For any other method, right, like, for example, this residual solvent method, they just are not adequate, okay, to look for those unknown peaks, okay.
Time again, you know, I mean, you know, based upon our retrospective investigation, you know, the GC-FID method is just -- you know, its intended -- its original intended purpose is to monitor those residual solvents. That's its intended purpose.

Page 256

So its intended purpose is not to, you know, identify, you know, any little, you know, you know, unknown peaks, right?
So, you know, and once again, as I mentioned, even as of today, in ICH Q3C, which is the most relevant ICH guidance governing the residual solvent, okay, even in that guidance today there is no specific requirement in terms of, you know, above what threshold an unknown peak need to be identified.
Q. One of the things that you need to know as a drug manufacturer is the limitations of GC-FID.
That's one thing you need to be aware of, right?
A. Well, it's all depends upon what's the intended purpose, right? So with the intended purpose for the residual solvents, the GC-FID method is perfectly suitable for that purpose.
Q. Well -- rephrase.
Here you had unknown peaks, didn't know what they were, according to the

Page 257

documents, and made a decision, it's a low amount, we don't have to be concerned.
That was the decision that was made, right?
A. Look, as I -- once again, you know, with the GC-FID method, okay, if you go into any pharmaceutical company, okay, including like my former, you know, employer, right, Merck & Company or any other, you know, like Schering-Plough, you know, these are the very famous, you know, multinational companies, okay, you know, people will not -- you know, for a residual solvent method, they will not going through every tiny little peaks to identify, you know, what they are, okay, you know, at least, you know, you know, before, you know, that event came out, right?
So -- so basically, you know, as I said, you know, it's -- you know, you will need to know, okay, and also it need to be above -- you know, like, for example, like in our conversation with Novartis or with some other, you know, you know, customers, right, they were, you know, also, at least

Page 258

some of them, they were not sure, you know, what a specific threshold, you know, it need to be set.

So, but from our perspective, if customer had that particular request for certain specific, you know, unknown peaks, yeah, we will do the investigation and try to, you know, identify or try to find, you know, the potential source, you know, you know, for those unknown peaks.

Q. It sounds like you're telling me it's really hard to find it, but Novartis, plus using an outside lab, they found the NDMA, and it wasn't even their drug substance. They found it before ZHP did on these chromatograms, is what you're -- and you're telling me it was too hard to figure it out?

A. Yes. Don't forget, these are the two different methods, okay? Two different methods, you know, you know, their critical, you know, method parameters, they are quite different. Okay.

Even for GC-FID, if you run on

Page 259

different instrument, sometimes, you know, the sensitivity can be vary quite a bit. Okay.

So, you know, and also, you know, some of our customer, they had a, you know, similar question regarding the unknown peaks, right? They also did a GC-MS analysis. Okay, they didn't, you know, find, you know, you know, NDMA.

I mean, and also we supply, you know, our product, right, with the zinc chloride. You know, I think shortly after the zinc chloride, you know, was approved by, you know, regulators, right, we supplied to Novartis', you know, subsidiary company, Sandoz, right. Sandoz, at least at that time, was part of Novartis.

So we supply Sandoz valsartan for quite, you know, long period. And so as a unit of Novartis, you know, they haven't had any, you know, you know, issues, or didn't, you know, even have questions, I think, as far as I understand, okay.

Q. Just to get back to my

Page 260

question, Novartis, enlisting the help of an outside lab, identified the NDMA, right? It wasn't so hard to do. They did it, right?

A. Look, we supplied Novartis, right, you know, all material like commercial skill batches, at least, you know, by the end of 2017, right. And they received, you know, a lot of those.

So from there, you know, I mean, I don't know why they, you know, you know, sended it to the outside lab or whatever.

So at least, you know, they -- usually, when you go into business trying to have a new, you know, vendor, you know, you will do the analysis or in-depth, you know, you know, analysis, you know, for the sample that you're going to be for your commercial, you know, productions.

So during that period, you know, Novartis, you know, their own lab, you know, still not was able to find. So my guess is, you know, once they contract this out to a certain lab, they just happen to be,

Page 261

you know, utilizing a different, you know, you know, method.

Okay. That method, it appears to be, you know, somewhat more sensitive than ZHP's method. Okay.

So if we -- you know, if someone would keep using that -- you know, you know, that condition that's originally intended for the GC-FID, you know, I think it's very fair to say, you know, NDMA, you know, at the -- you know, the level that's produced or that's present, you know, you know, you know, in ZHP's batches, you know, it was very difficult, if not entirely possible, I mean, to be adequately detected. Okay.

Q. You're aware that starting in 2014, complaints came in on a pretty regular basis from your customers pointing out unknown peaks and asking for answers.

You do know that there were multiple complaints and requests for information, right?

MR. GALLAGHER: Objection.

Page 262

Vague, and lacks foundation.
You can answer.
A. Yeah. I mean -- yeah, I mean, retrospectively, you know, you know, for some -- you know, you know, during the later stage of the investigation, you know, you know, yeah.
For example, with Novartis, also with Sun Pharma at the time, yeah, I was -- you know, later was also being consulted, you know, you know, how to, you know, address the origin or the identity.
But essentially, you know, it's the same set of the, you know, phenomenon, right? And so my guess is, you know, in our registered DMF or whatever, you know, the other kind of dossier, you know, you know, we just supplied to those customers, right, within -- you know, using the same set of documents, right?
And in those, you know, regulatory approved documents, you know, there was no, you know, specific information about, you know, some of those peaks. So

Page 263

that's why, you know, you know, some people, you know, they turn out to be having, you know, the same kind of question.
But again, you know, you know, based upon my, you know, knowledge, you know, first of all, you know, they -- initially at least, they all concentrated on relatively large peaks. And they ask for a certain specific, you know, set of peaks, right, and then we work with them, you know.
And also for some of the later coming in, you know, questions, we would sometimes utilize, you know, the previously, you know, obtained results to help answer.
For example, like in Novartis' cases, like I think we utilized some of the results, you know, we provided to Sun Pharma.
And again, you know, some of those company, they have been, you know, continuously, you know, you know, you know, buying, you know, commercial batches of -- you know, of, you know, valsartan, up to a point that, you know, we sent out the notice, you know, for suspension and also for recall.

Page 264

BY MR. SLATER:
Q. Coming back to my question, you're aware that there were multiple complaints made by customers in 2014, 2015, 2016, 2017, and 2018, saying that there were unknown peaks on their own testing, and they were looking for answers from ZHP as to what was the cause of those peaks.
That's a correct statement, right?
MR. GALLAGHER: Objection. Lacks foundation.
THE WITNESS: Sorry.
MR. GALLAGHER: Go ahead.
A. As I indicated, I didn't know, or I was not informed, you know, initially. And in some of those conversation, you know, late in the investigation, as I said, I was being consulted, you know, you know, or I was try -- you know, they tried to pull me to help them to find out, you know, you know, the identity or the potential sources.
BY MR. SLATER:
Q. All I'm asking is to confirm --

Page 265

rephrase.
All I'm looking to confirm right now is -- rephrase.
You can confirm for me that starting in 2014 with Ranbaxy and Sun Pharma, then Vertex, then Glenmark, then Sun Pharma, then Aurobindo, then Novartis, from 2014 to 2018, there were repeated customer complaints pointing to unknown peaks, correct?
MR. GALLAGHER: Objection. Vague, lacks foundation, asked and answered.
A. Some of those, they were treated as technical, you know, exchange, okay? And some of the customer, you know, you know, you know, at the time they, you know, they have this question, they were already, you know, receiving our commercial, you know, batches, as far as I know.
So they just wanted to know a little bit further, you know, the identity of, as I said, a certain specific numbers of unknown peaks. Okay.
Every time -- I mean, you know,

Page 266

basically they are the same set of the unknown peaks, right?

And as I said, you know, the reason why different company ask, you know, those questions is, my guess is probably because, you know, in our, you know, official documents, right, like the DMF or some other, you know, regulatory approved documents, you know, in there, there was, you know, no information on some of those, like, very small peaks. So -- you know, so, yes.

So it's the same kind of questions, and every time, as I said, we tried to do, you know, what we can to identify these peaks.

I think, you know, in the end, you know, we -- for all of the concerned peaks, you know, I think, you know, we were able to find the identity or the potential sources.

Q. You realize these companies that were complaining to ZHP about these unknown peaks, they weren't asking for the information because they were curious. They

Page 267

were asking what those peaks represented because they had quality obligations and GMP obligations and wanted to make sure that the substance they were purchasing from ZHP met the quality standards and was safe.

That's why they were asking, right?

MR. GALLAGHER: Objection. Lacks foundation, and calls for speculation.

A. It's a continuous process for improvement. And, you know, that's why, you know, you know, we understand our customers' concerns, right?

That's why every time, you know, they have a question, we responded, you know, and we trying to resolve, you know, the issue as well as, you know, possible.

And particularly during my, you know, you know, review of some of the documents, you know, with Novartis, you know, I think like in late May 2018, you know, there's one e-mail from Novartis, you know, they -- you know, they thank us, you know, to

Page 268

get the results, you know, they need like very -- you know, very quickly.

But, you know, again, as I said, those regulatory document, you know, we have the agency or regulatory, you know, approve the specification at the time.

BY MR. SLATER:

Q. The responsibility for the quality of the valsartan API was ZHP's responsibility, right?

A. Yes.

Q. And despite -- rephrase.

Despite that, Novartis identified the NDMA before ZHP did in June 2018, right?

A. It's the third-party lab, okay, and they -- you know, initially, you know, they tentatively identified, and they communicated it to us.

And upon the receipt of the information, we immediately, you know, purchased the reference materials, developed method, and -- yeah, so we very quickly confirmed their results.

Page 269

And also, within a very short period of time, we developed an adequate quantitative methods. So we will be able to very quickly to come up with, you know, you know, quite reliable NDMA results, okay, in those, you know, batches, particularly those batches, you know, you know, we discussed with Novartis.

Q. Well, just to be clear, ZHP already knew that the NDMA was in the valsartan, we've already established that, at least as of July 2017.

A. As I told you, at that time, you know, Mr., you know, Lin's, you know, e-mail, you know, as I said, it looks like didn't go far.

So company as a whole, you know, it didn't have that knowledge until, you know, receiving that Novartis, you know e-mails.

Q. Well, what happened was Novartis figured out that there was NDMA there, enlisting the services of a third-party lab to help it, and then

Page 270

basically told ZHP that ZHP needed to take the steps to notify the authorities and take steps to deal with the severe quality problem.

That's the only reason ZHP told anybody what happened here, was because Novartis pushed you to do it, right?

A. No.

MR. GALLAGHER: Objection. Vague, lacks foundation.

BY MR. SLATER:

Q. If Novartis had not come along, there's no reason to believe that ZHP would have told anybody about the NDMA, right?

MR. GALLAGHER: Objection.

A. That's your speculation.

MR. GALLAGHER: Lacks foundation.

BY MR. SLATER:

Q. We know that in July of 2017, it was discussed in an e-mail that valsartan had NDMA in it, and ZHP didn't tell anybody about that, right?

A. My answer -- you know, I think

Page 271

I already answered that question multiple times.

Q. Well, let's look right in the middle of the page where we just went through this -- well, rephrase.

Looking now at the middle of this page in Exhibit 213, the FDA Warning Letter of November 2018, it says, "Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA."

And then they point out, the FDA says, "For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms where the presence of NDMA was suspected to elute."

So -- and then they say -- just to be clear, they say, "At the time of testing, you considered this unidentified peak to be noise and investigated no further." So I want to stop there.

Page 272

You certainly would agree with me that the FDA's right; that you stopped your investigation before figuring out the answer, and then it was only when Novartis figured it out that the answer came out, right?

MR. GALLAGHER: Objection. Mischaracterizes testimony, and lacks foundation.

You can answer.

A. Let me give you a -- I try to give you a full answer, okay, part by part or little by little. Okay?

The FDA statement, the first one says, "Your response states that NDMA was difficult to detect," okay?

So this was -- FDA's basically repeating our language at the time, right? Okay. If you look at, you know, Dr. Janet Woodcock's statement, okay, she released during January -- in January 2019, right after, you know, this event came out, in that, you know, statement, you know, there is one sentence, something like, you know, it

Page 273

said, the -- like, the property of NDMA made it difficult to be detected by, like, a normal or routine analytical test method. Something like that. Okay.

So, you know, so basically combining everything that I told you, you know, with the GC-FID method, okay, you know, again, you know, you know, this peak, right, that I -- you know, that we told, you know, this particular inspector, right, the peak eluting after the toluene, you know, as I said, this is not NDMA.

NDMA is just -- yeah, just at the noise level, you know. As I said, at the NDMA in the real sample, you know, it was just among the smallest, you know, peaks, okay. So it's -- you know, it's just that -- you know, at that kind of level.

So that's -- you know, that's exactly what happened. I mean, all right. So you know, basically, again, as I indicated, you know, the nature of the GC-FID method is not designed to detect, you know, such low level peaks. Its purpose is to

Page 274

monitor, you know, the residual solvents that, you know, that one particular process utilized, you know, in that process.

So from that perspective, you know, that GC-FID residual solvent method is still, you know, suitable. Okay. I think that, you know, we're still utilizing this residual solvent method, okay, to release the valsartan API or drug substances, okay, to, you know, European, you know, customers, after we modify, you know, the process of valsartan API.

BY MR. SLATER:

Q. ZHP modified its SOPs so that following this revelation to the public about the NDMA, now you're required to use GC-MS to identify unknown peaks as a matter of course, right?

MR. GALLAGHER: Objection to form.

A. Well --

BY MR. SLATER:

Q. That's what the SOP says now, right?

Page 275

A. Our SOP -- yeah, because of -- yeah, based upon -- yeah, based upon the investigation, or the outcome, you know, of the investigation, our SOP now requires any unknown peaks, okay, with a signal-to-noise greater than 10 would be investigated, okay? And both FDA and also regulatory agency, they agree with this threshold, okay? So that's number one, all right?

And since then we have done tremendous, you know, you know, amount of testing utilizing GC-MS, even GC-MS/MS, right, and we have done so many tests. And so far we were not able to find another nitrosamine, you know, you know, you know, with this approach. Okay?

Q. Well, if you're talking about batching going forward, you were required to optimize the process so you wouldn't form nitrosamines, right?

A. Nitrosamine could still be present, okay, based upon the nature of the chemistry. Okay? It all depends upon how much, right?

Page 276

Right now, you know, I can tell you it's way below the detection limit of the original detection limit that we established, you know, after these events, because, as I mentioned to you in the very beginning, FDA, you know, the original position was it should be absent, right?

So based upon FDA's, you know, published analytical method for NDMA as well as for NDEA, and for NDMA the FDA's, you know, limit of quantitation is 5 ppb, okay. For NDEA the limit was 1 ppb, right? So our valsartan now is able to meet both, you know, you know, you know, requirement.

Although, as I said, you know, you know, FDA has basically retreated, you know, from their original position, right? Now it's being allowed, you know, you know, you know, for example, like for NDMA, now they allow, you know, 96 nanogram per day, which would translate into 300 ppb's, okay?

And so our product, our, you know, valsartan utilized this newly, you know, developed or modified process. Okay.

Page 277

We are able to generate, you know, you know, valsartan way below, you know, the 300 ppb, okay? So it's below, you know, you know, 5 ppb. So it's 60 times lower, you know, for the method, the detection limit.

MR. SLATER: Let's look at page 4 of the warning letter, Cheryll, if you're still there. Thank you. Okay. Could you scroll up a little bit more, please?

Q. Okay. Under number 2, the second paragraph, starting with the second sentence, the FDA advised you, "You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients."

My first question is, do you see what I just read?

A. Let's see. Which paragraph? I'm sorry.

Page 278

Q. Second paragraph under number 2.
A. Second paragraph. Oh, starting with "You also failed to," right?
Q. Yes.
A. Okay. Let me read through. I'm sorry. It's getting a little bit too long. You also... okay.
(Witness reviewing document.)
A. So I don't know, you know, whether this is specifically referenced here. If here, you know, FDA specifically, you know, referring to NDMA issue, I think this is in a statement, you know, after the fact.
Q. This is my question. You saw what I just read, right?
A. Yeah. I read through the second paragraph, yes.
Q. You would agree with me that that is a correct statement of ZHP's responsibilities under good manufacturing practices, right?
A. See, the precondition here is you need to know, or you have that knowledge,

Page 279

at the time of the process change. So that process change was made somewhere around 2011 to 2012.
Q. The point is, you would agree that ZHP, like any drug manufacturer, is responsible to use -- develop and use "suitable methods to detect impurities when developing, and making changes to, manufacturing processes."
You agree with that statement, right?
A. If during that period, right, during that initial development time, if someone, you know, involved in -- you know, in that, you know, development of that process, yeah, if they knew, they would develop a suitable method.
Q. And you also agree that "If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients"?
You agree with that statement, right?

Page 280

A. As I said, if it's a general statement, right. You know, for any -- like a regular, you know, impurity that really being, you know, appropriately detected like it was any -- like, you know, what we called a related substance method, you know, you know, or whether, you know, we will do the impurity, you know, identifications. I mean...
Q. ZHP was required to fully evaluate the impurities and take action to ensure that the valsartan was safe for patients. That you'll agree with, right?
A. Again, you know, if we knew at the time, you know, yeah, we will do that, yes.
Q. Well -- rephrase.
MR. SLATER: You know what? Now we can break.
MR. GALLAGHER: Okay.
MR. SLATER: Off the record.
THE VIDEOGRAPHER: The time right now is 1:07 p.m. We're now off the record.

Page 281

(Whereupon, the deposition was adjourned.)

CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, Ph.D., was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____

MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

Dated: April 20, 2021

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ACKNOWLEDGMENT OF DEPONENT

I, _________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
Min Li, Ph.D. Date

Subscribed and sworn
To before me this
______ day of _______________, 20____.

My commission expires: _______________

____
Notary Public

LAWYER'S NOTES

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